EXHIBIT A

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

GE HEALTHCARE BIO-SCIENCES AB and GLOBAL LIFE SCIENCES SOLUTIONS USA LLC Plaintiffs, v. BIO-RAD LABORATORIES, INC., Defendant.	C.A. No. 18-1899-CFC

CLAIM CONSTRUCTION ORDER

Consistent with the reasoning set forth on the record during the May 14, 2020 claim construction hearing, the Court rules that, as used in the asserted claims of U.S. Patent Nos. 9,671,420, 9,709,589, 9,709,590, 9,709,591 and RE47,124, the following terms have the following meanings:

I. AGREED-UPON CONSTRUCTIONS

Claim Term(s)	Agreed Upon Construction
"CPU" / "CPU unit"	"central processing unit"
"the fluidics section is external to the housing and the non[-]fluidics section is internal to the housing"	"the fluidics section is on the outside of the housing and the non-fluidics section is on the inside of the housing"

II. DISPUTED CONSTRUCTIONS

Claim Term(s)	Court's Construction
"interchangeable modular component"	"component that can be inserted into and removed from positions in the housing and that has a standardized size and shape that allows it to be exchanged with another component"
"interchangeable modular fluid handling unit"	"fluid handling unit that can be inserted into and removed from positions in the housing and that has a standardized size and shape that allows it to be exchanged with another fluid handling unit"
"modular fluid handling unit"	"fluid handling unit that has a standardized size and shape that allows it to be exchanged with another fluid handling unit"
Claim Preambles ("An automated liquid chromatography system comprising"/ "A method of modifying a fluid flow path in an automated liquid chromatography system comprising"/ "A method for building an automated liquid chromatography system, the method comprising"/ "A liquid chromatography system arranged to provide a controlled fluid flow through a chromatography column, the system comprising")	The preambles are claim limitations.
"liquid chromatography system"	Plain and ordinary meaning
"automated liquid chromatography system"	Plain and ordinary meaning

Claim Term(s)	Court's Construction
"wherein the system is capable of performing automated liquid chromatography"	Plain and ordinary meaning
"non-fluidics section"/"non-fluidics section"/"non fluidics section"	"a section of the interchangeable fluid handling unit that includes electrical components and does not include fluidics components"
"a fluid handling section"/"a fluidics section"	"a section of the interchangeable fluid handling unit that includes fluidics components and does not include non-fluidics components"

SO ORDERED THIS 28th day of May, 2020,

United States District Judge

EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CYTIVA SWEDEN AB, and GLOBAL LIFE SCIENCES SOLUTIONS USA LLC, Plaintiffs v. BIO-RAD LABORATORIES, INC., Defendant.	C.A. No. 18-1899-CFC Consolidated **DEMAND FOR JURY TRIAL** **HIGHLY CONFIDENTIAL (TECHNICAL) – ATTORNEYS' EYES ONLY**

REBUTTAL EXPERT REPORT OF DR. BRUCE GALE

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Exhibit 5	(Filed Under Seal) BRGE00000846 - 864
Exhibit 5	(Filed Under Seal) BRGE00000846 - 864
Exhibit 6	(Filed Under Seal) BRGE00000572 - 597
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Exhibit 16	(Filed Under Seal) BRGE00000748 - 784
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Exhibit 20	U.S. Publication No. 2008/0035542 ("Mourtada")
Exhibit 21	U.S. Patent No. 5,766,460 ("Bergstrom")
Exhibit 22	U.S. Publication No. 2008/0233653 ("Hess")
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Exhibit 27	07.23.2020 Chapman Depo Tr.
Exhibit 28	06.24.2020 Hareland Depo Tr.
Exhibit 29	[redacted]
Exhibit 30	[redacted]

performing the specific chromatography techniques they require in order to, for example, purify proteins for use in their research. The specific form factor, or the form of modularity that the system employs is secondary, at best, in a user's assessment of what liquid chromatography system will be capable of satisfying their needs. A user will never buy a system that is not able to perform the chromatography techniques required. In other words, function is far more important than form to a user of liquid chromatography systems. As I stated above, the patents in suit are not directed to performing any new aspect of chromatography or performing any existing aspect of chromatography in any new way. Rather the patents are simply directed to form factor or aesthetic aspects of chromatography. The machine is likely to ship more easily as a single unit rather than as multiple boxes. But I do not consider this to be any type of technological advance.

V. CLAIM CONSTRUCTION

20. I understand that the Court has entered a Claim Construction Order.[1]

21. I understand that the parties agreed on the following constructions relevant to the Asserted Patents discussed in this report.

Terms	Agreed Construction
"CPU" / "CPU unit"	"central processing unit"
"the fluidics section is external to the housing and the non[-]fluidics section is internal to the housing"	"the fluidics section is on the outside of the housing and the non-fluidics section is on the inside of the housing"

22. I understand that the Court has construed the disputed terms as follows.

Terms	Court's Claim Construction
"interchangeable modular component"	"component that can be inserted into and removed from positions in the housing and that has a standardized size and shape that allows it to be exchanged with another component"
"interchangeable modular fluid	"fluid handling unit that can be inserted into and

[1] D.I. 89.

handling unit"	removed from positions in the housing and that has a standardized size and shape that allows it to be exchanged with another fluid handling unit"
Claim Preambles ("An automated liquid chromatography system comprising" / "A method of modifying a fluid flow path in an automated liquid chromatography system comprising" / "A method for building an automated liquid chromatography system, the method comprising"/ "A liquid chromatography system arranged to provide a controlled fluid flow through a chromatography column, the system comprising")	The preambles are claim limitations.
"liquid chromatography system"	Plain and ordinary meaning
"automated liquid chromatography system"	Plain and ordinary meaning
"wherein the system is capable of performing automated liquid chromatography"	Plain and ordinary meaning
"non-fluidics section" / "non-fluidics section" / "non fluidics section"	"a section of the interchangeable fluid handling unit that includes electrical components and does not include fluidics components"
"a fluid handling section" / "a fluidics section"	"a section of the interchangeable fluid handling unit that includes fluidics components and does not include non-fluidics components"

23. In all cases, I applied the agreed claim constructions or the Court's constructions as one of ordinary skill in the art would interpret them in light of the specification and the file history in performing my analyses and rendering my opinions in this report.

24. In this regard, it is my opinion that Dr. Wereley has misconstrued the Court's claim construction at least with respect to the terms fluidics section and non-fluidics section in Paragraphs 57-58 of his report. He has done so, apparently, because he did not state in his opening report that he reviewed the file history where the inventors of the asserted patents made certain statements explaining what their inventions were not. By failing to review those statements, Dr. Wereley interprets the Court's claim construction (and statements made during

the hearing that are not part of the claim construction) in a way which is inconsistent with the inventors' statements during the prosecution. I will address these issue more particularly with respect to certain elements but address them here in a general manner as well.

25. Dr. Wereley quotes isolated portions of what I understand to be the hearing transcript from the claim construction proceedings to claim that there can be non-fluidics (electronics) outside the non-fluidics section of each module. (Wereley Report ¶57). But what the portion of the hearing transcript that Dr. Wereley quoted did not say is that electronics of the module can be in the fluidics section, even if they are not in the non-fluidics section. Ex. 3, Markman Hearing Tr., 97:16-25. All it says is that it may be possible for there to be electronics that are not in the fluidics section that are also not in a non-fluidics section. *Id.* That does not mean that once can indiscriminately define electrical components as being in some section that is neither a fluidics section or a non-fluidics section for purposes of establishing infringement. By failing to review the file history and see how the inventors interpreted what a "section" is, Dr. Wereley is interpreting the claims and asserting infringement against the Bio-Rad devices in ways that are inconsistent with the word section in the asserted patents and the representations the inventors made to the patent office to obtain their patent. By doing so, Dr. Wereley is also interpreting the random passages he was presented from the claim construction hearing in an improper way.

26. For example, the judge stated at pages 90-91 of the hearing transcript after counsel went through some, but not even all, the statements in the file history that the inventors made to obtain their claims that there was clear and unmistakable representations by the inventors that the electrical components should be separated from the fluidic components:

THE COURT: -- I think Mr. Bilsker makes a compelling argument that looks pretty clearly and unequivocally, your client, or the applicant for the patent I should say made clear, clearly and unequivocally, as far as I'm concerned, that there are two sections, and that's what differentiates this patent from Bergstrom and Hess. So why don't you walk me through your response to that.

MR. MILLER: Okay. So, first of all, I think it's important to note that we don't disagree that there's going to be a separation from the fluidics section and non-fluidics section, but, first of all, there can be other sections.

As you pointed out, the claim language talks about a fluidics section and a non-fluidics section, and all the claims use the transitional phrase comprising, which means there can be other sections.

So even if you draw the circle --

THE COURT: That wasn't how you distinguished Bergstrom and Hess. I mean, you pretty explicitly said to the Examiner, hey, what makes this different is we've got

complete separation of the fluidic and the non-fluidic section. And, incidentally, I think that's consistent with, you know, your slide, which says, hey, the phrase itself tells you, there's no fluidic component in the non-fluidic section.

MR. MILLER: Well, our argument on non-fluidics in the fluidics section, that's what I called the non-fluidics section.

THE COURT: As opposed to the fluidics section. I mean, it's a referential definition. Right? It says, this is a non-fluidics section as opposed to the fluidics section.

27.

28. The Court then reiterated at pages 102-103 of the hearing transcript, the clear and unequivocal statements that the inventors had made to obtain their patents and about there needing to be two sections: a fluidics section and a non fluidics section and there had to be complete separation between the fluidics and the electronics in them:

I'm going to interpret non-fluidics section to mean, "a section of the interchangeable fluid handling unit that includes electrical components and does not include fluidics components."

I'm going to construe a fluid handling section to mean, "a section of the interchangeable fluid handling unit that includes fluidics components and does not include non-fluidics components." And that seems to me to be the

most reasonable construction. That is consistent with what I think were clear and unequivocal statements to distinguish this patent from Bergstrom and Hess, because the basis of the distinctions to the Patent Examiner were that this patent had two sections that, at least two sections, one is non-fluidic, one is fluidic, that are separated completely and that do not contain components of the other section.

That does not, however, preclude the possibility that there are other sections that are in the invention, and that's important because that is consistent with the use of the indefinite article, which is inconsistent with Bio-Rad's insistence that "all," either fluidic or non-fluidic components, are in the respective handling unit.

So that actually seems to me is the right result in this case and I'm going to construe then these last group of terms in that manner.

29. All right. Is there anything else for me to

30. Again, just because there is a theoretical possibility that there may be yet a third or forth section where there could be an electrical or fluidic component, does not mean that any component that is encountered that is inconsistent with an infringement theory can be dealt with by claiming it is in a "section" that is distinct from what is otherwise a fluidics or non fluidics section. Any creation of this alternative additional section that is inconsistent with how the inventors construed the prior art is not permissible and Dr. Wereley failed to consider that in any way in his opening report.

31. I note that relevant portions of the file history that inform that a section cannot be defined as Dr. Wereley has tried to do in his infringement report appear as Ex. G in the joint claim construction briefing which I understand has the Document number DI 52-8 (Ex. 19)[2]. I will be referring to pages from that Exhibit G, which I incorporate into this report as well as the Mortada, Ex. 20, Bergstrom Ex. 21, and Hess Ex. 22 references discussed in those pages of the File History. I will also refer, when necessary to the slides that counsel used during the claim construction hearing to illustrate points from the File History.

VI. SUMMARY OF OPINIONS

32. As set forth in detail below, based on my review of the Asserted Patents, including the Asserted Claims and the prosecution histories of the Asserted Patents, the claim constructions in this matter, the accused products and functionality the Wereley and Vukicevic Reports, and the materials listed in Exhibit 1, I have reached the following opinions:

- The accused products do not directly or indirectly infringe, any asserted claim of the '420 patent;
- The accused products do not directly or indirectly infringe, any asserted claim of the '589 patent;

[2] For clarity, I refer to the original exhibit identification Exhibit G throughout. But Exhibit G is Exhibit 19 here.

42. Moreover, when one of ordinary skill in the art performs an analysis of the patent, the statements the inventors made to obtain their patents, and the actual modules that have been accused, they would only be able to come to the conclusion that there is no external fluidics section in the two pump and one injection valve module that Dr. Wereley has relied on to prove infringement of this element.

43. Throughout the specification of the asserted patents, the inventors stress that there needs to be separation of fluidics and electronics components to ensure that electronics are not harmed when changing fluid connections and when a leak occurs. *See, e.g.*, Col. 2: 28-32 (a liquid handling panel to separate fluidics and electronics); Col 6: 17-620(in one embodiment, the panel member essentially separates the fluidics section from the electronics and internal electronics); Col. 6: 10-29 (noting various arrangements, including with and without a panel member such that the electronics are separated from the fluidics through the use of such components as a suitable sealing arrangement between the housing opening and the external fluidics side of the module); Col. 7:7-25 (noting air tight sealing between the component positions and the non fluidics section and noting configurations, such as that claimed, where fluids are strictly on one side of the fluid handling panel and the electronics are strictly on the other: "According to one embodiment, fluids are strictly restricted to the fluidics section 30 of the interchangeable modular components 26, but in alternative embodiments , only fluid connections are restricted to the fluidics section 30 allowing fluid to "cross" the fluid handling panel inside the non-fluidics section 30 of the interchangeable modular component 26.")

44. I note that nowhere in the patent is there a description of anything other than two sections in a module, a fluidics section and a non-fluidics section. To the extent there is some other intermediate section, it is nowhere described in the patents or how to determine it.

Nonetheless, even if one of skill in the art were to assume that such a section could exist, they would recognize that such a section would need to satisfy the goals of the invention, which is to keep the fluids separate from the electronics. Dr. Wereley never considered this requirement, which is present not only in the passages cited above, but also by the named inventor Mr. Lundkvist, Cytiva's previous expert, Dr. Scandella, and statements that the inventors made during prosecution to obtain the patents.

45. [redacted]

60. The inventors said the separation requirement was even more important in liquid chromatography systems as opposed to other automated fluid handling systems: "The features of claim 17 as applied to liquid chromatography are particularly advantageous because such a system is typically used for many different initial experiments to prove the principles for larger scale operations. In such use, the system components are frequently reconfigured and in so doing the advantages of fluid and non-fluid separation, as claimed in claim 17 become even more significant, for example by providing a housing for liquid chromatography components including a liquid handling panel for accepting the components and avoiding contamination of electrical components." Ex. G at GEHC 001418.

61. To ensure that the goals of the invention were met, the inventors described in great detail during the prosecution when they were distinguishing the prior art what was necessary to separate the fluidics from the non-fluidics sections and what would not be considered separation – something that still had a likelihood of the electronic components of a module becoming wet when fluid connections were changed, modules were rearranged, or a leak occurred. If that was possible, then one of skill in the art would recognize that the fluidics and the non fluidics (electronics) were not in distinct sections that were separated. Rather they would be in the same section.

62. And as will be explained in more detail in the following paragraphs that is what is present in the Bio-Rad accused modules. One of ordinary skill in the art reading the file history would only be able to come to the conclusion that the external electronics that Dr. Wereley recognizes are present in the accused Bio-Rad modules (the two pumps and injection valve, Wereley ¶ 116) are not in sections that are distinct from the fluidics sections. Rather, they are in the same section and not separated in the manner the inventors said they needed to be to be part

of the invention and distinct from the prior art. For example, the accused pump module has switches, a display, and LED lights which the user sees, as well as a PCB and ribbon electrical connector in the overlay. *See e.g.*, Wereley ¶ 142, showing pictures of accused pumps in Ex. 48, 49 and ¶ 150 quoting from manual Ex. 47 stating that there are switches on the exterior of the pump modules. *See also* Ex. 25.

63. In particular, the inventors pointed out that for there to be separation of the electrical components and the fluidic components of a module such that they were in separate sections and unlikely to have fouling/wetting or contamination of the electrical components if there was a leak of the fluidic components, there had to be a particular spatial relationship between the components.

64. In particular, the inventors said multiple times that the fluidics and the electronic components of a module need to be on opposite sides of a panel for a) them to be separated, b)to ensure that the electronics would not get wet if there was a leak, and c) to define the electronics and the fluidics as being in separate sections. In discussing Bergstrom, the inventors said: "The modules of Bergstrom do not separate their fluidic and electrical parts (where they have electrical parts). Further, those paths cross into the base plate at about the same region. The detector module 10 of Figure 10 illustrates that fluid and electrical parts are adjacent, **not on either side of a panel.** Ex. G at GEHC 001451.

65. After stating that Bergstrom gives no thought to making sure that electrical parts do not get wet, which I cited to above, the inventors then reemphasize, one paragraph later, the separation point and again state that the fluidic and electronic parts need to be on opposite sides of a panel in the invention. In fact they not only state that the electronic parts in a modules need to be on opposite sides of one panel, but on opposite sides of two different panels : "These

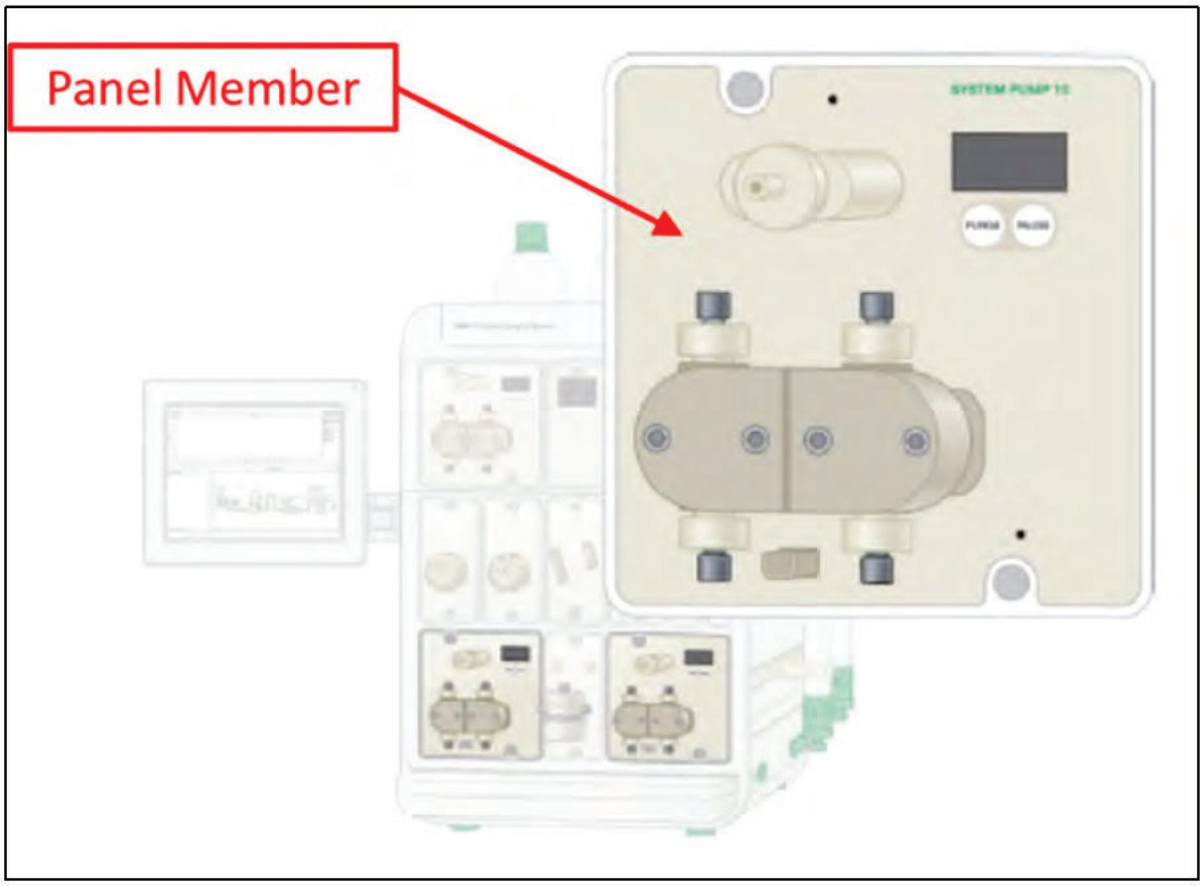
problems in the Bergstrom design are not addressed in Burger, but are cleverly addressed in presently claimed invention **by separating** the fluidic and non fluidic parts of fluid handling units **across a fluid handling panel** and **across a panel member of the modular components**, **which inhibits the problems mentioned immediately above**." *Id.*

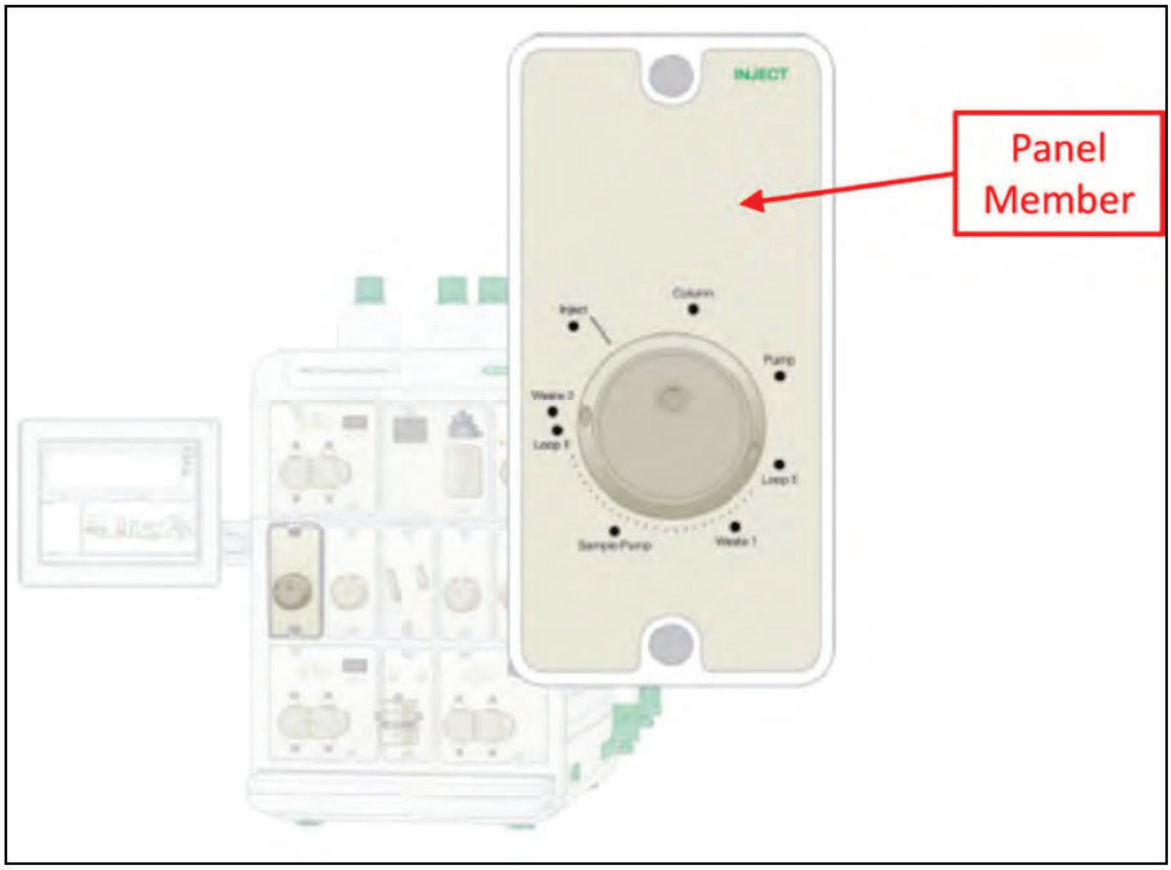
66. The accused modules do not meet those requirements for multiple reasons and therefore do not have external fluidics sections, ones that do not have electrical components, for multiple reasons.

67. First, having failed to refer to any of the File History statements which require the fluidics components of a module to be separated from the electrical components by at least two different panels to be considered by one of ordinary skill in the art to have distinct fluidics and electronics sections, Dr. Wereley provides no detailed analysis of the alleged panel member of the modules that are supposed to separate fluidics from electronics components of a module to meet the requirement that the electronics and fluidics are in separate sections.

68. Dr. Wereley purports to analyze the panel member as claim element 1(h) at paragraphs 138- 147. But the analysis is cursory and conclusory again. At paragraphs 139 and 141, Dr. Wereley pastes pictures of a Bio-Rad system pump and a sample inject valve and simply draws a red arrow and red box and concludes these are the panel members of the modules. I reproduce those figures below:

69.





70.

71. At paragraph 145, Dr. Wereley cites to testimony from two Bio-Rad witnesses to establish that what he has pointed to is a panel member. But, the testimony does not do so. Both Mr. Bland, and Mr. Chapman, whose testimony is quoted, state that the component that Dr. Wereley points to as the panel member is actually two separate parts: there is 1) "a front plate" and an "overlay" *Id.* at ¶ 145. Mr. Chapman testified that [redacted] *Id.* at p. 91 (quoting Chapman testimony).

72. In other words, Mr. Chapman's testimony makes clear that the faceplate is what is responsible for allowing the module to be mounted on the instrument housing. I have confirmed this by holding and physically examining a number of the Bio-Rad modules. The specification of the asserted patents describes the panel member as the structure that is used to attach the module to a component position in the in the liquid handling panel. *See e.g.*, '420 patent Col. 6:30-34 ("As is disclosed in FIGS. 4a to 4d, the interchangeable modular components 26 comprises a panel member arranged to separate the fluidics section from the non fluidics section and for attachment to a component position in the liquid handling panel.")

73. The first problem with Dr. Wereley's analysis is that he equates two distinct parts, the [redacted] and calls them collectively the panel member. *See* Wereley at ¶ 146, referring to the [redacted] The assembly drawing from one exemplary module, which is how all the modules are created, shows that the [redacted], and it is the [redacted] which attaches to the housing and would properly be called the panel member.

74. 

Ex. 6, BRGE00000582.

75. As one can see in the figure above for the inject valve, there is a hole between the two red circles at the top and the bottom. Those holes are where the screws are inserted to attach the module to the housing. That structure on the left side of the picture is what one of ordinary skill in the art reading the specification and looking at the accused product would call the panel member as it is what attaches the module to the housing.

76. The [redacted] which is on the right side of the figure is attached to the [redacted]. One can see from the figure that the overlay is full of electronics. There is a [redacted] which appears brown or copper colored. There is a ribbon wire connector, and there are LED lights shown on this module. Other modules also have a display that the user can see as well as switches for the user to activate. The

LED lights, the display and the switches are not trivial elements added to avoid infringement as I understand plaintiff's counsel portrays them. Rather the LED lights tell a user where to make fluidic connections and the display enables users to easily see values and parameters on the modules. The switches allow the user to manually control the purge and priming capabilities of the pumps. See Wereley ¶ 160, citing Ex. 47, "1 Product Description" of Analytical Preparative Pump Module. [redacted] and Bio-Ra employees have pointed out that it is a feature which users like and appreciate. Ex. 27, Chapman Depo Tr. at 206:21-207:13.

77. In any event, given that the [redacted] are two separate structures held together by a [redacted], one of ordinary skill in the art would not consider them collectively the panel member.

78. But, even if one of ordinary skill in the art reading the specification considered the overlay and faceplate to be the panel member, they would not consider the electronics that are part of the overlay to be in a separate section of the module from the fluidics section as Dr. Wereley concludes with no analysis. At paragraph 149 of his report, Dr. Wereley merely says: "I see no reason why the fact that certain of the modules have LEDs or displays integrated into their panel members takes them outside the scope of the claim language. For one, as discussed, the fact that these are non-fluidics components is not relevant since under the Court's claim construction, only the fluidics section cannot have non-fluidics components such as electronics, and the panel member is a different section in that it is neither a 'fluidics section' nor a 'non-fluidics section'."

79. Dr. Wereley makes the statement that he does not see any reason why the electronics "integrated into the panel members takes them outside the scope of the claim language without analyzing the file history to see how the inventors characterized their invention and how they treated what is a fluidics section. When the file history is examined, one of ordinary skill in the art can only come to the conclusion that what Dr. Wereley points to as a panel member and a fluidics section of the accused modules do not satisfy the requirements of the claims and are not consistent with how the inventors characterized their invention or the fluidics section in the file history. As a result, Dr. Wereley's opening report fails to meet Plaintiffs' burden of establishing the existence of this element in the accused modules.

80. Dr. Wereley merely concludes with absolutely no analysis that anything "integrated into the panel member" is a different section from the fluidics and electronics sections. I do not agree and neither would one of ordinary skill in the art who read the specification and the file history.

81. First, the inventors addressed this very issue in the file history. With respect to fluidics and electronics and the existence of separate sections, the inventors stated that the fluidics and the electronics need to be on either side of a panel. *See* Ex. G GEHC 001451 (The detector module 10 of Figure 10 illustrates that the fluid and electrical parts are adjacent, **not on either side of a panel"**) (emphasis added); ("Bergstrom has given no thought to what happens when one unplugs a module and gets the electrical contacts 19 wet which will be inevitable since the contacts 19 appear to be housed in the cup shaped aperture 14… These problems in the Bergstrom design are not addressed in Burger, but are cleverly addressed in presently claimed invention **by separating the fluidic and non-fluidic parts of fluid handling units** across **a**

fluid handling panel and across **a panel member of the modular components**, which inhibits the problems mentioned immediately above.")(emphasis added)

82. The first quote from the inventors in the above paragraph shows that they consider the panel member, which like all physical objects has a thickness, has two sides, (*i.e.* "either sided"). It is apparent Dr. Wereley did not consider this fact. If he did, Dr. Wereley could not make the accused panel member consistent with the inventor statements by claiming that rather than two sides, the panel member has four sides: 1) the side the user sees, 2) the inner side of that side in the thickness of the panel, 3) the side that is mounted against the housing, 4) the inner side of that side which is also in the thickness of the panel. In standard English usage, which does not differ from the way one of ordinary skill in the art would understand what the inventors said, "either" indicates two options.

83. The same conclusion would be reached by one of skill in the art reading the second quote from Ex. G at page GEHC 1451 that I quoted above that the inventors made regarding the arrangement of the fluidics and electronics of a module. In the second quote, again distinguishing Bergstrom, the inventors stated that the fluidics must sit "**across**" two different panels: 1) the fluid handling panel and 2) the panel member. The accused products satisfy neither of these requirements and would not be considered by one of ordinary skill in the art to therefore contain a fluidics section with no electronics in the section.

84. As with the word "**either**" in the first quote, one of ordinary skill in the art would understand the use of the word "**across**" with reference to the fluidics and electronics of a panel being across two different panels to refer to the panel having two sides and the electronics and fluidics of a module lying on the opposite sides. That is not the case with the accused modules

85. According to Dr. Wereley, the electronics are "embedded" in the panel member and thus part of a separate section from the fluidics. In addition to the fact that this embedded notion is inconsistent with the two statements I quoted above stating that the fluidics and electronics should be on either side of the panel member and across two different panels, the liquid handling panel, which the electronics and fluidics in the accused modules surely are not, and the panel member which they also are not – it is also inconsistent with other statements and the physical arrangements of the components in the Bergstrom reference that the inventors distinguished.

86. In the file history, the inventors stated that one can see how Bergstrom arranged his components in Figs. 1 and 4(a) where you can see a flow line 5 in baseplate 1. Ex. G at GEHC 1449. I reproduce those figures and others from Bergstrom (Ex. 21) below.

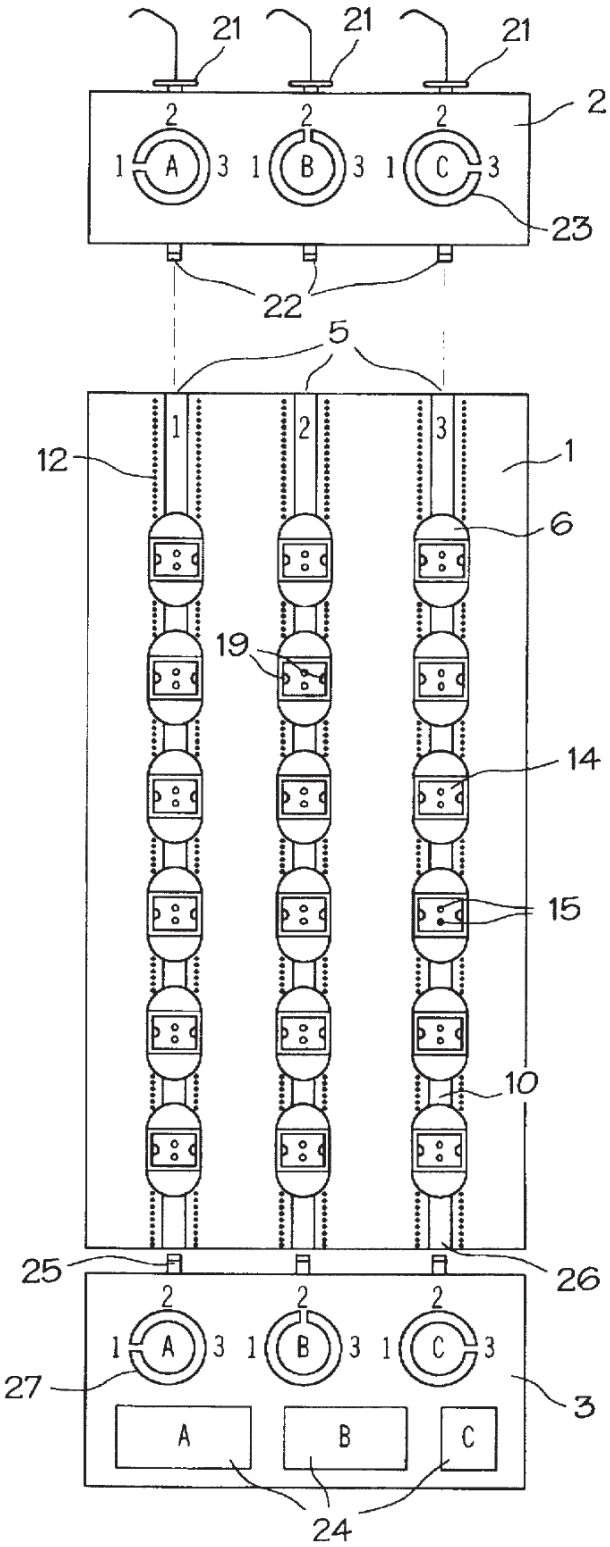

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FIG. 1

87.

88. The inventors repeatedly described the flow line "5" as being adjacent to the electrical connectors "12" and therefore, having fluidics which are not separated from the electronics in the base plate "1" which had been equated to the panel member. Ex. G, GEHC at 1449-1451.

89. Dr. Wereley's claim that electronics integrated in the thickness of the panel member are in a separate section and separated from the fluidics section of the module is inconsistent with what the inventors said about Bergstrom. As can be seen in Figure 4(a), which I reproduce below and which the inventors referenced when distinguishing Bergstrom as not having separate fluidics and electronics sections that were separated, the electronics lines "12" in Bergstrom are integrated in the base plate/panel member and are distanced from the fluid lines "5" which are also embedded in the base plate.

90. In Fig. 4(a) one sees a blow up of a single module "10" in base plate "1". One can see in the figure that the flow line "5" is within the thickness of the base plate

91. This is also shown in Fig. 2 which I also reproduce below.

92. as

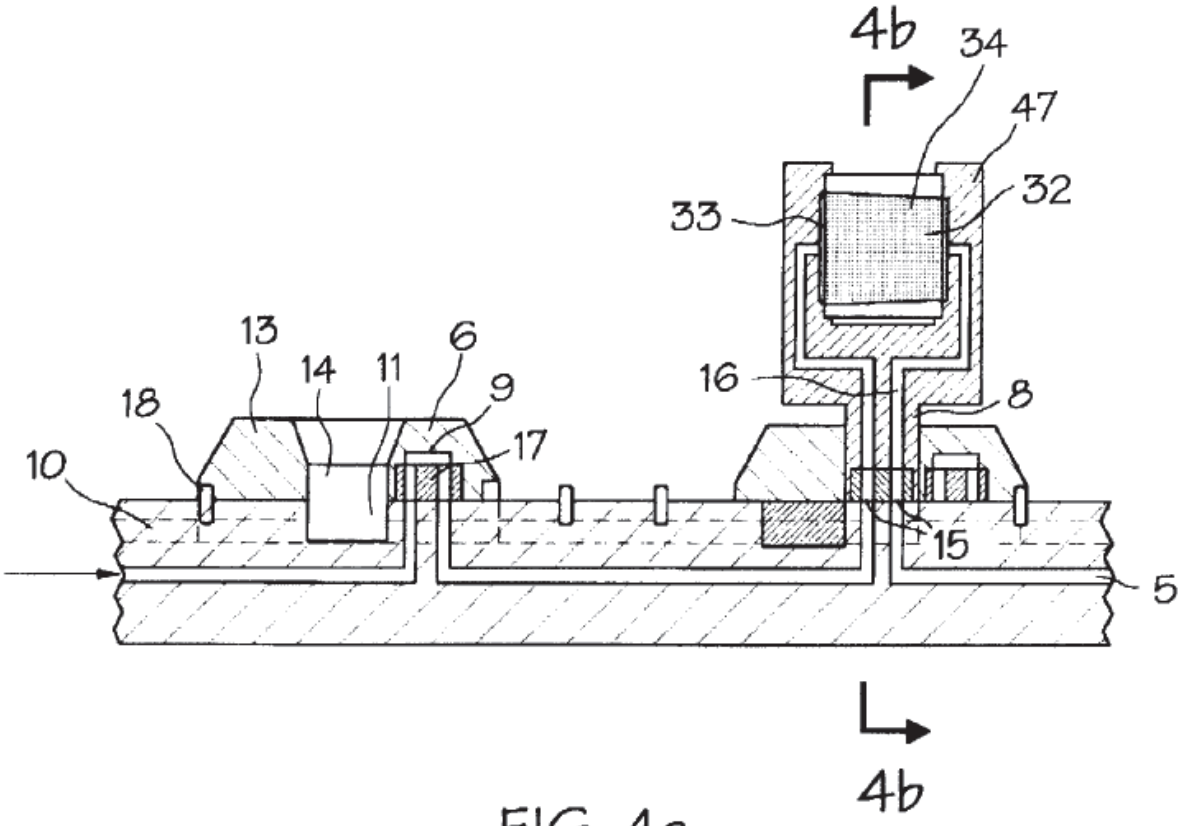


FIG. 4a

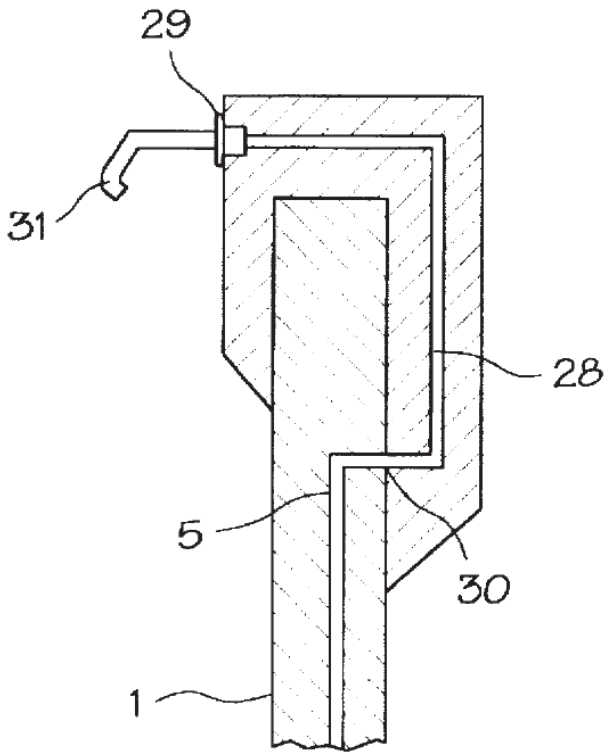


FIG. 2

93.

94. Similarly, the Bergstrom specification states that the electrical lines "12" which are depicted in Fig. 1, are also embedded in baseplate 1. *See* Ex. 21 Bergstrom 5,766,460 at Col. 3:50-54 (One or more lines/conductors (**12**) for signal and power transmissions from or to connected modules may be arranged in the base plate (**1**) preferably along the flow lines (**5**).". Nonetheless, even though the electronics were integrated in the thickness of the baseplate/panel member and so too were the fluid lines (5). Although those lines were parallel or near each other, they would have to be embedded in different thickness of the baseplate/panel member. But, consistent with the prior statements of the inventors that the fluids and electronics in a module had to be on different sides of two different panels, the inventors did not consider Bergstrom to have modules with separate fluid and electronics sections or have those sections separated.

95. Consequently, Dr. Wereley's analysis that having electronics integrated in the thickness of the panel member creates a different section that is separated from the fluidics section, is not consistent with the file history and one of ordinary skill would not come to the same conclusion that Dr. Wereley did. Rather, after reading the portions of the file history I have discussed thus far, one of ordinary skill in the art would conclude that the accused modules do not have an external fluidics section—one that has no electrical components.

96. Dr. Wereley's analysis that integrated electronics are a separate section from the fluidics does not consider at all that such an analysis fails to account for the accused devices and the analysis regarding them being inconsistent with the purpose of the invention. As I detailed previously, the patent, the inventor and plaintiff's prior experts also stressed that the purpose of the invention was to have electronics and fluidics in distinct sections that are separated and sealed from each other so as to keep the fluids from wetting or damaging the electronics such as when fluid connections are being changed or if there is a leak. That is not the case in the accused devices.

97. As I explained above and as can been seen in the photo of the assembly procedure for the inject valve that I reproduced in this report, the overlay attaches to the face plate only with a few drops of glue. That method of attachment is not sufficient to seal the electronics which Dr. Wereley says are "integrated " in the "panel member" from fluids on the module. To confirm this, I physically examined at least two different modules recently, a pump module and a pH module with respect to the relationship between the overlay and the faceplate. I confirmed by looking at these physical samples that fluid that leaks from the modules would not be sealed from the electronics Dr. Wereley describes as being integrated in the panel member.

113. At best, (which I do not agree with) what Dr. Wereley describes as electronics integrated in the panel member to create a section distinct from the fluidics section would be an example of individual protection of fluidics from electronics in each module that the inventors distinguished their invention from over Hess. Such individual protection does not provide the "collective protection" that the inventors said was necessary in their invention. In other words, the electronics integrated in each panel member of each module in the Bio-Rad accused modules and system are not protected from the fluidics by being inside a housing that protects them all. Rather the integrated electronics that Dr. Wereley points to are each protected individually.

114. A person of ordinary skill in the art reading the inventors' statements about Hess would recognize that if in Hess, a single electronic cable exiting the back of a module, in which the cable was spaced apart from the fluidics at the front of the module by at least two walls and a much greater distance than the electronics in the Bio-Rad accused devices are distanced from the fluidics, did not constitute a distinct section that was separated from the fluidics section, then neither does what Dr. Wereley calls the electronics integrated in the panel member of the accused modules.

115. For these reasons, the accused devices do not have an external fluidics section. Similarly, the subsequent elements that I will discuss in the following paragraphs relating to the non fluidics section and the separation of the fluidics from the non fluidics by a panel member and the non fluidics section being internal to the housing and separated from the fluidics by a liquid handling panel when the module is inserted into the housing are also not met.

2. Element [1.f]: "an internal non-fluidics section"

116. Element [1.f] of the '420 patent requires "an internal non-fluidics section."

117. The NGC System does not infringe this element because the NGC System does not include "an internal non-fluidics section" as required by claim 1 of the '420 patent. As

detailed with respect to element 1(e) in the prior paragraphs, which I incorporated herein, each of the Bio-Rad accused modules contain either LED lights, a display or both that are visible to the user and on the same side of the panel member as the fluidics. The pump modules also have electronic switches on the same side of the panel member as the fluidics. They also contain electronics such as a PCB and ribbon line in the "overlay" shown in the assembly documents cited and that are exhibits to this report. These are all part of the non-fluidics section and cannot simply be considered a separate section from the electronics that are inside the housing.

118. In paragraphs 118- 126 Dr. Wereley concludes that there is a non fluidic section, one that he believes does not have fluidics, by pointing to electronics inside the housing. But, as discussed previously, Dr. Wereley does not at all consider the File History. As I discussed previously regarding element 1(e), when the file history is examined, one of ordinary skill in the art can only come to the conclusion that there is not a non fluidics section in the accused Bio-Rad modules.

119. For example, the Hess reference certainly had electronics that were sealed in a box and separated from the fluidics that were outside the housing and on the front face visible to the user. *See* Ex. G at 1423 ("Since the Hess design was conceived with radioactive product processing in mind [e.g. see abstract] the need for sealing each box and electrically connecting each box such that liquid radioactive contamination does not penetrate the boxes or box electrical interconnections is very important, but results in a costly system."); *See* Figs. 2 and 4 reproduced above from the Hess reference showing the fluidics.

120. Nonetheless, as shown in the previous element, the inventors stated Hess was distinct from their invention because there was a single electrical component, a connector between modules, that exited from the back of each module. The inventors considered that

124. For all these reasons and those discussed with respect to element 1(e), the three accused Bio-Rad liquid handling units do not have a non fluidics section.

3. Element [1.h]: "a panel member arranged to separate the fluidics section from the non-fluidics section"

125. Element [1.h] of the '420 patent requires "a panel member arranged to separate the fluidics section from the non-fluidics section."

126. The NGC System does not infringe this element because the NGC System does not include "a panel member arranged to separate the fluidics section from the non-fluidics section" as claimed. I incorporate my discussion of the prior two elements for this element. In summary, the electronics in the housing are not a separate non-fluidics section from the electronics Dr. Wereley describes as integrated in the panel member. "Integrating" as shown with the arrangement of Bergstrom, does not create separate sections. There is no way to square the representations the inventors made about Mourtada, Bergstrom and Hess with respect to separation, with the arrangement in the Bio-Rad accused modules that have electronics adjacent to and on the same side of the panel member as the fluidics. At a minimum, the electronics that Dr. Wereley describes as being integrated in the panel member are the fluidics in the Bio-Rad accused modules, which are not on "either side" of the panel member as the inventors said they must be. Ex. G at 1451 ("The detector module 10 of Fig. 10 illustrates that fluid and electrical parts are adjacent **not on either side of a panel."**)(emphasis added).

4. Element [1.i]: "wherein the housing comprises a liquid handling panel with at least four component receiving positions arranged in a two dimensional array and adapted to receive said interchangeable modular components such that, when inserted, the fluidics section is external to the housing and the non-fluidics section is internal to the housing."

127. Element [1.i] of the '420 patent requires "wherein the housing comprises a liquid handling panel with at least four component receiving positions arranged in a two dimensional

array and adapted to receive said interchangeable modular components such that, when inserted, the fluidics section is external to the housing and the non-fluidics section is internal to the housing."

128. I have discussed why this element is not met with respect to my discussion of elements 1(e), 1(f) and 1(h). I incorporate those discussions fully for this element.

129. The NGC System does not infringe this element because the alleged housing lacks the underlined portions of the claim element: "a liquid handling panel with at least four component receiving positions arranged in a two dimensional array and adapted to receive said interchangeable modular components such that, when inserted, the fluidics section is external to the housing and the non-fluidics section is internal to the housing."

130. In summary, the failure of proof for this element is most easily demonstrated with reference to the inventors' discussion of the Hess reference. As discussed with respect to elements 1(e) and 1(f), in the Hess reference, each module had electronics sealed in a box and fluidics visible from a side that one can consider the front of the box. The inventors pointed out that what the examiner was considering the modules also had a single electrical connection exiting the back of the box. *See e.g.*, ¶¶ 107-112 herein. For this reason, they concluded that Hess did not have a non fluidics section internal to said housing and a fluidics section external to said housing. There is no way for one of ordinary skill in the art to distinguish the arrangement in Hess that the inventors said was outside the scope of their invention with the arrangement in the accused modules. In the accused modules, there are electronics outside the housing. Those electronics cannot be a section that is distinct from the electronics that are inside the housing, just like the single electronic connection in Hess was not distinct from the electronics contained in the sealed boxes. Because the electronics inside the sealed boxes in Hess, that the examiner

considered a housing did not constitute a non fluidics section that was internal to said housing when inserted, one of ordinary skill in the art could not also consider the electronics that Dr. Wereley considered to be embedded in the panel member to be a non fluidic section that is distinct from the electronics that are inside the housing in the Bio-Rad accused modules.

131. Therefore, Dr. Wereley has failed to meet his burden to establish the existence of this element in the accused fluid handling modules.

5. Element [1.k]: "wherein each interchangeable modular component includes a dedicated cpu unit allowing the interchangeable modular component to independently perform operations in response to instructions over the system bus"

132. Element [1.k] of the '420 patent requires "wherein each interchangeable modular component includes a dedicated cpu unit allowing the interchangeable modular component to independently perform operations in response to instructions over the system bus."

133. The NGC System does not infringe any claims of the '420 patent because the alleged interchangeable modular component lacks "a dedicated cpu unit allowing the interchangeable modular component to independently perform operations in response to instructions over the system bus" as claimed.

134. In particular, Dr. Wereley, at paragraphs 160-170 of his report where he discusses this element, has not established and met his burden of proof that each module acts independently to perform operations after receiving instructions over the bus. First, I do not believe that Dr. Wereley has used the proper definition of the CPU's on the modules acting independently. Second, I do not see proof under the definition that he does use that each of the accused modules acts independently of other modules.

135. Dr. Wereley interprets the "independent" language in the claim to mean independent of other modules. *See* Wereley ¶167. But that is not how one of ordinary skill in

the art would interpret that limitation. The specification gives two alternatives for control. First it describes the master control unit communicating with each module over a bus and those control signals issued by the MCU controlling the modules. *See* Col. 7: 57-60 ("As mentioned above, the chromatography system may comprise a master control unit 40 arranged to communicate with all modular components e.g. 1-26 over a system bus 42 such as a CAN-bus or the like"). In that embodiment, something other than a CPU on the module would instruct the module what to do. The control function could be carried out by for example a particular voltage/current that would make a pump operate at a certain rate. (e.g., A high signal makes the motor operate at one rate and a low signal makes it operate at another rate).

136. Alternatively, the specification indicates that each module could also have a CPU that would allow the module to independently perform operations in response to instructions over the bus. *See* col. 7: 60-63 ("In one embodiment, each modular component is provided with a dedicated CPU unit allowing the component to independently perform operations in response to instructions over the BUS 42.") One of ordinary skill in the art would not read that alternative to do nothing more than take the signal that the master control unit has sent and forward it. For example, if the master control unit sent out a signal that would deliver a certain voltage or current to a module to make it operate at a certain level (e.g., A high or low signal), one of ordinary skill in the art would not read the specification to mean that the CPU would take an instruction and merely forward it to another device to create that same current or voltage or simply translate that instruction into a different format.

137. Rather, one of ordinary skill in the art would understand the passage in the specification relating to the independent operation of the CPU to mean that a signal is received from the master control unit and then the CPU does something above and beyond what that

signal indicates and what the MCU would have done on its own, something that is independent of the signal the MPU sent.

138. One example of that would be the function described for the 2040 instrument which I detailed in my invalidity report. In the 2040, the burette modules have a CPU located directly on them. The 2040 User Manual indicates that the burette modules have very precise control – the ability to vary flow in one of 10,000 increments. To maintain such precise control, one of ordinary skill in the art would recognize that the burette module, using its CPU is independently monitoring the flow value and constantly making adjustments to ensure the set value is being maintained. In that situation, the CPU on the burette is operating independently of the master control unit which would have only sent the original instruction for what the initial parameter should be.

139. Given that the specification describes the back to back situations where either: 1)the Master Control Unit controls the operation of the module, and contrasts that with 2) the situation where the CPU independently controls an operation of the module in response to an instruction from the MCU, one of ordinary skill in the art would not understand the independent control to be control that is independent of what is occurring in other modules as Dr. Wereley does.

140. Contrary to what Dr. Wereley concludes at paragraph 167, the mention of the MCU and the fact that the MCU needs to send instructions would not lead one of ordinary skill in the art to interpret independently to mean independent of other modules just because the CPU must receive some signal from the MCU. The fact that some signal needs to go from the MCU to the CPU does not mean that all the functions carried out by the CPU have to be controlled directly in response to individual discrete commands from the MCU. As I explained in the

158. Therefore, Dr. Wereley, Mr. Vukicevic and Plaintiffs have failed to establish the existence of this element in the accused devices. .

7. Element [1.m]: "wherein said housing is adapted to accommodate at least one pump, at least one sensor unit and at least two fluid control valves of different configurations, of which at least three of the pump, the sensor unit and the fluid control valves are interchangeable modular components"

159. For the reasons stated previously the sample inject module and the two system pump modules are not interchangeable modular components because the interchangeable modular components of claim 1 need to have the fluidics and non fluidics sections of elements 1.e and 1.f as well as the separation requirements of elements 1 (h, i, j) and the independent operations requirements of element 1.k and identification requirement of 1(l) which the sample inject module and the two pump modules do not have as described previously which I incorporate herein. The same is true for the other fluid handling modules that Dr. Wereley identifies as alternatives to the pump and inject valve for this element.

160. Further, with respect to the UV module that Dr. Wereley relies on to satisfy this claim element, he identifies a sensor unit, but neither the Bio-Rad single or multi-wavelength UV detectors qualifies as interchangeable modular units that can satisfy this element because neither has the required fluidics and non fluidics sections, a panel member for separating those sections, and a liquid handling panel for separating those sections, nor does either satisfy the requirement that the electronics be internal to the housing when inserted.

161. One of ordinary skill in the art reading the file history, specification and claims would conclude that the Bio-Rad single and multi-wavelength detectors are not interchangeable modular units as required by the claims. In fact, the inventors addressed this very type of component and unequivocally stated that such a detector did not come within the claims of its invention.

179. Given the statements of the inventors, the testimony of Dr. Scandella and the images of the UV and conductivity detector, one of ordinary skill in the art could not conclude that the UV/Conductivity modules have: fluidics and non fluidics sections, that they have a panel member that separates the fluidic from non fluidic sections, that they have a liquid handling panel that separtes fluid from non fluidics, that the non fluidic electronic section is internal to the housing when inserted into the respective cavity of the housing. I have confirmd in conversations with Joe Hilario that [redacted] . For at least all these reasons, the UV/Conductivity module cannot meet this claim element. I did not see any other sensor unit that Dr. Wereley relied on to meet the sensor limitation, but even if he did, all the sensor units that Bio-Rad can use in the accused systems contain the same arrangement as the UV/Conductivity modules. There are electronics that are part of the modules that are on the outside of the housing and on the same side of the panel member as the fluidics. Thus, such sensor units would not meet the limitations of the claims for the reasons already described previously for the liquid handling units. Moreover sensor units such as the PH detector contain additional electronics that are part of the module, external rather than internal to the housing and on the same side of the panel member as the fluidics. The PH detector has an electrode that is placed in contact with fluid and is part of the module. Thus the PH detector module cannot meet this limitation of claim 1 or the limitations of claim 5 below.

180. Many of the subsequent claims contain the same limitations and whether or not specifically stated, the arguments made thus far are specifically incorporated and become part of the argument for the subsequent limitations as well.

8. Dependent Claim 5: "further comprises a pH electrode that is external to the housing"

181. Claim 5 depends from claim 1, and requires that the recited liquid chromatography system "further comprises a pH electrode that is external to the housing."

182. I have discussed why this element is not met with respect to my discussion of element 1.e. and the last element discussed above for claim 1(m). I incorporate those discussions fully for this element. Therefore, the "pH electrode" is not "external to the housing" as required.

9. Dependent Claim 6: "that the at least two fluid control valves include an injection valve, a column valve with integrated pressure sensors, a quaternary valve, an inlet valve, a sample inlet valve, a pH valve, or an outlet valve"

183. Claim 6 depends from claim 5, and requires "that the at least two fluid control valves include an injection valve, a column valve with integrated pressure sensors, a quaternary valve, an inlet valve, a sample inlet valve, a pH valve, or an outlet valve."

184. I have discussed why this element is not met with respect to my discussion of element 1.e. and the other elements of claim 1. All of the fluid handling modules in the Bio-Rad accused devices are structured in the same way as the pump and inject valves I discussed with claim 1 and cannot meet the elements of that claim for the same reasons. Further, as discussed above with regard to element 1(m) all of the sensor units or modules used in the Bio-Rad accused devices have the same general structure. In addition to the types of electronics identified for the fluid handling units, all the sensor units have further electronics outside the housing which are used to perform the sensing function.

inserted, the fluidics section is external to the housing and the non-fluidics section is internal to the housing"

192. See corresponding element of claim 1 which I incorporate herein. Element

15. Element [17.xi]: "wherein each interchange modular component includes a dedicated CPU unit allowing the interchangeable modular component to independently perform operations in response to instructions over the system bus"

193. Element [17.xi] of the '420 patent requires "each interchange modular component includes a dedicated CPU unit allowing the interchangeable modular component to independently perform operations in response to instructions over the system bus."

194. I have discussed why this element is not met with respect to my discussion of element 1.k . I incorporate those discussions fully for this element.

195. In summary, a person of ordinary skill in the art would not read this limitation to mean that the "modular fluid handling unit" cpu does nothing more than take the signal that the master control unit has sent and forward it. For example, if the master control unit sent out a signal that would deliver a certain voltage or current to a module to make it operate at a certain level (*e.g.*, A high or low signal), one of ordinary skill in the art would not read the specification to mean that the CPU would take an instruction and merely create that same current or voltage or simply translate that instruction into a different format.

196. Rather, one of ordinary skill in the art would understand the passage in the specification relating to the use independent operation of the CPU to mean that a signal is received from the master control unit and then the CPU does something above and beyond what that signal indicates and what the MCU would have done on its own, something that is independent of the signal the CPU sent.

16. Element [17.xiii]: "wherein said housing is adapted to accommodate at least one pump, at least one sensor unit, and at least two fluid control valves of different configurations, of which at least two of the

211. Element [27.k] of the '420 patent requires "each interchangeable modular component includes a dedicated CPU unit allowing the interchangeable modular component to independently perform operations in response to instructions over the system bus."

212. I have discussed why this element is not met with respect to my discussion of element 1.k of the '420 patent. I incorporate those discussions fully for this element.

213. In summary, a person of ordinary skill in the art would not read this limitation to mean that the "modular fluid handling unit" cpu does nothing more than take the signal that the master control unit has sent and forward it. For example, if the master control unit sent out a signal that would deliver a certain voltage or current to a module to make it operate at a certain level (*e.g.*, A high or low signal), one of ordinary skill in the art would not read the specification to mean that the CPU would take an instruction and merely create that same current or voltage or simply translate that instruction into a different format.

214. Rather, one of ordinary skill in the art would understand the passage in the specification relating to the use independent operation of the CPU to mean that a signal is received from the master control unit and then the CPU does something above and beyond what that signal indicates and what the MCU would have done on its own, something that is independent of the signal the CPU sent.

24. Element [27.m]: "wherein said housing is adapted to accommodate at least one pump, at least one sensor unit and at least two fluid control valves of different configurations, of which at least two of the pump, the sensor unit, and the fluid control valves are interchangeable modular components"

215. For the reasons stated previously the sample inject module and the two system pump modules are not interchangeable modular components because the interchangeable modular components of claim 1 need to have the fluidics and non fluidics sections of elements 1.e and 1.f as well as the separation requirements of elements 1 (h, i, j) and the independent

operations requirements of element 1.k and identification requirement of 1(l) which the sample inject module and the two pump modules do not have as described previously which I incorporate herein.

216. In summary, with respect to the UV module that Dr. Wereley points relies on to satisfy this claim element, he identifies a sensor unit, but neither the Bio-Rad single or multi-wavelength UV detectors qualifies as interchangeable modular units that can satisfy this element because neither has the required fluidics and non fluidics sections, a panel member for separating those sections, and a liquid handling panel for separating those sections, nor does either satisfy the requirement that the electronics be internal to the housing when inserted.

217. One of ordinary skill in the art reading the file history, specification and claims would conclude that the Bio-Rad single and multi-wavelength detectors are not interchangeable modular units as required by the claims. In fact, the inventors addressed this very type of component and unequivocally stated that such a detector did not come within the claims of its invention.

25. Dependent Claim 30: "the system further comprises a pH electrode that is external to the housing, and wherein the pH electrode is connected to a pH valve formed as an interchangeable modular component"

218. Claim 30 depends from claim 27, and requires that "the system further comprises a pH electrode that is external to the housing, and wherein the pH electrode is connected to a pH valve formed as an interchangeable modular component."

219. I have discussed why this element is not met with respect to my discussion of element 1.e and claim 5. I incorporate those discussions fully for this element. Therefore, the "pH electrode" is not "external to the housing" as required.

B. Non-Infringement of the '589 Patent

1. Element [1.d]: "wherein the housing unit comprises on one external side of the housing unit a plurality of receiving positions, each receiving position adapted to receive the modular fluid handling units therein such that a fluid handling section thereof is on the external side of the housing unit, the receiving positions being arranged in a two dimensional array"

220. Element [1.d]: "wherein the housing unit comprises on one external side of the housing unit a plurality of receiving positions, each receiving position adapted to receive the modular fluid handling units therein such that a fluid handling section thereof is on the external side of the housing unit, the receiving positions being arranged in a two dimensional array."

221. I have discussed why there is not fluid handling section in the accused products with respect to claim 1 of the 420 paten which I incorporate fully herein.

2. Element [1.g]: "wherein each modular fluid handling unit . . . includes a CPU for independently performing fluid control operations in response to instructions over a system BUS"

222. Element [1.g] of the '589 patent requires "wherein each modular fluid handling unit . . . includes a CPU for performing fluid control operations independently irrespective of the location within the housing unit."

223. See discussion for corresponding element of claim 1 of the 420 patent incorporated herein.

3. Element [6.f]: "each modular fluid handling unit includes a CPU for performing fluid control operations independently irrespective of the location within the housing unit"

224. See corresponding element of claim 1 of the 420 patent incorporated herein.

4. Dependent Claim 7: "housing unit is adapted to accommodate at least one pump, at least one sensor unit and at least two fluid control valves of different configurations, of which at least two of the pump, the sensor unit, and the fluid control valves are freely arrangeable modular fluid handling units"

225. Claim 7 depends from 6, and requires that the "housing unit is adapted to accommodate at least one pump, at least one sensor unit and at least two fluid control valves of different configurations, of which at least two of the pump, the sensor unit, and the fluid control valves are freely arrangeable modular fluid handling units."

226. I have discussed why this element is not met with respect to my discussion of claim 1 and element 1.e and dependent claims 5-6 of the '420 patent. I incorporate those discussions fully for this element.

5. Dependent Claim 8: "housing unit is adapted to accommodate at least one pump, at least one sensor unit and at least two fluid control valves of different configurations, of which at least two of the pump, the sensor unit and the fluid control valves are arranged as modular fluid handling units"

227. Claim 8 depends from 1, and requires that the "housing unit is adapted to accommodate at least one pump, at least one sensor unit and at least two fluid control valves of different configurations, of which at least two of the pump, the sensor unit and the fluid control valves are arranged as modular fluid handling units."

228. I have discussed why this element is not met with respect to my discussion of element 1.e and dependent claims 5-6 of the '420 patent. I incorporate those discussions fully for this element.

6. Dependent Claim 9: "the at least two fluid control valves include an injection valve, a column valve with integrated pressure sensors, a quaternary valve, an inlet valve, a sample inlet valve, a pH valve, and an outlet valve"

229. Claim 9 depends from claim 8, which in turn depends from claim 1, and requires that "the at least two fluid control valves include an injection valve, a column valve with integrated pressure sensors, a quaternary valve, an inlet valve, a sample inlet valve, a pH valve, and an outlet valve."

230. I have discussed why this element is not met with respect to my discussion of element 1.e and dependent claims 5-6 of the '420 patent. I incorporate those discussions fully for this element.

7. Dependent Claim 13: "the automatic liquid chromatography system further comprises a pH electrode that is external to the housing unit, and wherein the pH electrode is connected to a pH valve arranged as a modular fluid handling unit"

231. Claim 13 depends from claim 1, and requires that "the automatic liquid chromatography system further comprises a pH electrode that is external to the housing unit, and wherein the pH electrode is connected to a pH valve arranged as a modular fluid handling unit."

232. I have discussed why this element is not met with respect to my discussion of element 1.e and dependent claims 5-6 of the '420 patent. I incorporate those discussions fully for this element.

8. Dependent Claim 14: "the pH valve includes an integrated flow cell for in-line monitoring of pH levels"

233. Claim 14 depends from claim 13, and requires that "the pH valve includes an integrated flow cell for in-line monitoring of pH levels."

234. I have discussed why this element is not met with respect to my discussion of element 1.e and dependent claims 5-6 of the '420 patent. I incorporate those discussions fully for this element.

9. Dependent Claim 21: "the fluid handling section of the modular fluid handling unit is sealed from an internal side of the housing unit when fitted in a receiving position of the housing unit"

235. Claim 21 depends from claim 20, and requires that "the fluid handling section of the modular fluid handling unit is sealed from an internal side of the housing unit when fitted in a receiving position of the housing unit."

236. I have discussed why this element is not met with respect to my discussion of element 1.h of the '420 patent. I incorporate those discussions fully for this element.

237. The NGC System does not infringe this element because the NGC System does not include "a panel member arranged to separate the fluidics section from the non-fluidics section" as claimed. I incorporate my discussion of elements [1.e] and [1.f] for this element. In summary, the electronics in the housing are not a separate non-fluidics section from the electronics Dr. Wereley describes as embedded in the panel member. "Embedding" as shown with the arrangement of Bergstrom does not create separate sections. There is no way to square the representations the inventors made about Mourtada, Bergstrom and Hess with respect to separation, with the arrangement in the Bio-Rad accused modules that have electronics adjacent to and on the same side of the panel member as the fluidics. At a minimum, the electronics that Dr. Wereley describes as being embedded in the panel member are the fluidics in the Bio-Rad accused modules, which are not on "either side" of the panel member as the inventors said they must be. Ex. G at 1451 ("The detector module 10 of Fig. 10 illustrates that fluid and electrical parts are adjacent **not on either side of a panel."**)(emphasis added).

10. Dependent Claim 24: "a pH electrode that is external to the housing unit, and wherein the pH electrode is connected to a pH valve arranged as a modular fluid handling unit"

238. Claim 24 depends from claim 6, and requires "a pH electrode that is external to the housing unit, and wherein the pH electrode is connected to a pH valve arranged as a modular fluid handling unit."

239.

11. Dependent Claim 25: "the pH valve includes an integrated flow cell for in-line monitoring of pH levels"

240. Claim 24 depends from claim 24, which depends from claim 6, and requires "the pH valve includes an integrated flow cell for in-line monitoring of pH levels."

241. I have discussed why this element is not met with respect to my discussion of element 1.e and dependent claims 5-6 of the '420 patent. I incorporate those discussions fully for this element.

12. Dependent Claim 26: "the modular fluid handling units include two double piston pumps, one injection valve for injecting a sample onto a column connecting a flow path of the liquid chromatography system, a UV monitor, and a mixer"

242. Claim 26 depends from claim 6, and requires "the modular fluid handling units include two double piston pumps, one injection valve for injecting a sample onto a column connecting a flow path of the liquid chromatography system, a UV monitor, and a mixer."

243. I have discussed why this element is not met with respect to my discussion of element 1.e and dependent claims 5-6 of the '420 patent. I incorporate those discussions fully for this element.

C. Non-Infringement of the '590 Patent

1. Element [1.b]: "interchanging at least two of the interchangeable modular components in a housing unit comprising at least four component receiving positions arranged in a two dimensional array, so as to allow for modification of the liquid chromatography fluid flow path among the at least four interchangeable modular components"

244. Dr. Wereley has not shown that this element was met. I understand that in order to infringe this claim, which is a method claim the steps claimed need to have been performed. Additionally, they need to have been performed in the United States and after the 590 patent issued on January 18, 2017. I see no such proof offered in Dr. Wereley's report.

245. At paragraphs 491-507, Dr. Wereley states that he has seen videos of people changing modules. But he does not establish in his report where this alleged changing is

248. Element [1.c] of the '590 patent requires "wherein each of the at least four interchangeable modular components comprises a CPU unit for independently performing fluid control operations in response to instructions from a system controller when installed in a component receiving position of the housing unit."

249. The NGC System does not infringe claim 1 of the '590 patent because it lacks "at least four interchangeable modular components comprises a CPU unit for independently performing fluid control operations in response to instructions from a system controller when installed in a component receiving position of the housing unit."

250. I have discussed why this element is not met with respect to my discussion of elements 1.k of the '420 patent. I incorporate those discussions fully for this element.

251. In summary, a person of ordinary skill in the art would not read this limitation to mean that the "modular fluid handling unit" cpu does nothing more than take the signal that the master control unit has sent and forward it. For example, if the master control unit sent out a signal that would deliver a certain voltage or current to a module to make it operate at a certain level (*e.g.*, A high or low signal), one of ordinary skill in the art would not read the specification to mean that the CPU would take an instruction and merely create that same current or voltage or simply translate that instruction into a different format.

252. Rather, one of ordinary skill in the art would understand the passage in the specification relating to the use independent operation of the CPU to mean that a signal is received from the master control unit and then the CPU does something above and beyond what that signal indicates and what the MCU would have done on its own, something that is independent of the signal the CPU sent.

3. Claims 2 and 3, Flow path shortened

253. None of the evidence that Dr. Wereley cited shows that even if modules are interchanged, the flow path is shortened. The same is true for the evidence he cited for claim 3. Thus, he failed to meet his burden on these claims.

4. Claims 10 and 12

254. Dr. Wereley has not met his burden to establish infringement of these claims. While he says the steps claimed could be done, he points to nothing where these steps were actually done in the United States after Jan. 18, 2017. That is what is necessary to establish infringement of this method claim. For this reason, he has not met his burden to show infringement.

5. Element [13.h]: "comprising a CPU that allows independent fluid control operations in response to instructions from the main controller when installed in the component receiving position of the housing unit**"**

255. Element [13.h] requires "the at least two interchangeable modular fluid handling units … compris[e] a CPU that allows independent fluid control operations in response to instructions from the main controller when installed in the component receiving position of the housing unit"

256. I have discussed why this element is not met with respect to my discussion of element 1.k of the '420 patent. I incorporate those discussions fully for this element.

257. In summary, a person of ordinary skill in the art would not read this limitation to mean that the modular component's cpu does nothing more than take the signal that the master control unit has sent and forward it. For example, if the master control unit sent out a signal that would deliver a certain voltage or current to a module to make it operate at a certain level (*e.g.*, A high or low signal), one of ordinary skill in the art would not read the specification to mean that the CPU would take an instruction and merely create that same current or voltage or simply translate that instruction into a different format.

258. Rather, one of ordinary skill in the art would understand the passage in the specification relating to the use independent operation of the CPU to mean that a signal is received from the master control unit and then the CPU does something above and beyond what that signal indicates and what the MCU would have done on its own, something that is independent of the signal the CPU sent.

6. Claim 14 "adding an expansion housing unit that includes a plurality of component receiving positions, each component receiving position being adapted to receive the at least one interchangeable modular fluid handling unit, and placing at least one additional interchangeable modular fluid handling unit in one of the component receiving positions in the expansion housing"

259. While Dr. Wereley states that the elements of these claims could be done, he does not cite evcidence showing that the expansion housings were used. Nor does he show any use in the United States after January 18, 2017. He has therefore failed to meet his burden to establish infringement.

7. Claim 17: "the CPU allows for automatic identification by the liquid chromatography system upon placement in a component receiving position of similar size and shape"

260. I do not agree with Dr. Wereley that the CPU does need to do the identification. In any event, the testimony that Dr. Wereley cites and his conclusion about infringement of this claim are inconsistent with the conclusions he reached in corresponding claims of the 420 patent where he stated that the MCU was doing the identification. I incorporated the arguments I made with respect to that claim. Moreover as with the other claims in this patent he has not shown that the method was actually performed in the U.S. at the proper time.

8. Claim 18: "the at least two interchangeable modular fluid handling units are connected to the system by a system BUS"

261. Dr. Wereley has not provided any evidence showing that this step was performed in the U.S. at the proper time to establish infringement. Therefore he has failed to meet his burden of proof.

D. The '591 Patent

1. The NGC System Does Not Infringe Claim 9 of the '591 Patent at Least Because it Lacks Several Elements in Claim 1 from Which it Depends

262. Claim 9 depends on claim 1. I note that claim 1 of the '591 patent is nearly identical to claim 1 of the '420 patent. Thus, I incorporate my analysis of claim 1 of the '420 patent.

(a) Element [1.v]: an external fluidics section

263. Element [1.v] requires "an external fluidics section."

264. I have discussed why this element is not met with respect to my discussion of element 1.e of the '420 patent. I incorporate those discussions fully for this element.

(b) Element [1.vi]: an internal non fluidics section

265. I have discussed why this element is not met with respect to my discussion of element 1.f of the '420 patent. I incorporate those discussions fully for this element.

(c) Element [1.viii]: "a panel member arranged to separate the fluidics section from the non-fluidics section"

266. Element [1.viii] of claim 1 of the '591 patent requires "a panel member arranged to separate the fluidics section from the non-fluidics section."

267. The NGC System does not infringe claim 9 at least because it lacks "a panel member arranged to separate the fluidics section from the non-fluidics section," as claimed.

268. I have discussed why this element is not met with respect to my discussion of element 1.h of the '420 patent. I incorporate those discussions fully for this element.

269. The NGC System does not infringe this element because the NGC System does not include "a panel member arranged to separate the fluidics section from the non-fluidics section" as claimed. I incorporate my discussion of elements [1.e] and [1.f] of the '420 patent for this element. In summary, the electronics in the housing are not a separate non-fluidics section from the electronics Dr. Wereley describes as embedded in the panel member. "Embedding" as shown with the arrangement of Bergstrom does not create separate sections. There is no way to square the representations the inventors made about Mourtada, Bergstrom and Hess with respect to separation, with the arrangement in the Bio-Rad accused modules that have electronics adjacent to and on the same side of the panel member as the fluidics. At a minimum, the electronics that Dr. Wereley describes as being embedded in the panel member are the fluidics in the Bio-Rad accused modules, which are not on "either side" of the panel member as the inventors said they must be. Ex. G at 1451 ("The detector module 10 of Fig. 10 illustrates that fluid and electrical parts are adjacent **not on either side of a panel."**)(emphasis added).

(d) Element [1.ix]: "wherein the housing comprises a liquid handling panel with two or more component receiving positions adapted to receive said interchangeable modular components such that, when inserted, the fluidics section is external to the housing and the non-fluidics section is internal to the housing"

270. Element [1.ix] of claim 1 of the '591 patent requires "wherein the housing comprises a liquid handling panel with two or more component receiving positions adapted to receive said interchangeable modular components such that, when inserted, the fluidics section is external to the housing and the non-fluidics section is internal to the housing."

271. The NGC System does not infringe claim 9 at least because it lacks "wherein the housing comprises a liquid handling panel with two or more component receiving positions adapted to receive said interchangeable modular components such that, when inserted, the

fluidics section is external to the housing and the non-fluidics section is internal to the housing," as claimed.

272. I have discussed why this element is not met with respect to my discussion of elements 1.e and 1.f of the '420 patent. I incorporate those discussions fully for this element.

(e) Claim [1.xi]: "wherein each interchangeable modular component includes a dedicated CPU unit allowing the interchangeable modular component to independently perform operations in response to instructions over the system bus"

273. Dependent claim [1.xi] requires "wherein each interchangeable modular component includes a dedicated CPU unit allowing the interchangeable modular component to independently perform operations in response to instructions over the system bus."

274. The NGC System does not infringe claim 9 at least because it lacks "wherein each interchangeable modular component includes a dedicated CPU unit allowing the interchangeable modular component to independently perform operations in response to instructions over the system bus," as claimed.

275. I have discussed why this element is not met with respect to my discussion of element 1.k of the '420 patent. I incorporate those discussions fully for this element.

276. In summary, a person of ordinary skill in the art would not read this limitation to mean that the modular component's cpu does nothing more than take the signal that the master control unit has sent and forward it. For example, if the master control unit sent out a signal that would deliver a certain voltage or current to a module to make it operate at a certain level (*e.g.*, A high or low signal), one of ordinary skill in the art would not read the specification to mean that the CPU would take an instruction and merely create that same current or voltage or simply translate that instruction into a different format.

277. Rather, one of ordinary skill in the art would understand the passage in the specification relating to the use independent operation of the CPU to mean that a signal is received from the master control unit and then the CPU does something above and beyond what that signal indicates and what the MCU would have done on its own, something that is independent of the signal the CPU sent.

2. Dependent Claim 26: "the pH electrode is connected to a pH valve formed as an interchangeable modular component"

278. Claim 26 depends from claim 12, and recites that "the pH electrode is connected to a pH valve formed as an interchangeable modular component."

279. I have discussed why this element is not met with respect to my discussion of element 1.e of the '420 patent. I incorporate those discussions fully for this element.

3. Dependent Claim 27: "the pH valve include[] an integrated flow cell for in-line monitoring of pH levels"

280. Claim 27 depends from claim 26, and further requires that "the pH valve include[] an integrated flow cell for in-line monitoring of pH levels."

281. I have discussed why this element is not met with respect to my discussion of element 1.e of the '420 patent. I incorporate those discussions fully for this element.

E. Non-Infringement of the '124 Patent

1. Element [16.h]: "a panel member arranged to separate the fluidics section from the non fluidics section and for attachment of the modular component to a component position of the liquid handling panel."

282. Element [16.h] requires "a panel member arranged to separate the fluidics section from the non fluidics section and for attachment of the modular component to a component position of the liquid handling panel."

283. The NGC System does not infringe claim 16 at least because it lacks "a panel member arranged to separate the fluidics section from the non fluidics section and for attachment of the modular component to a component position of the liquid handling panel," as claimed.

284. I have discussed why this element is not met with respect to my discussion of element 1.h of the '420 patent. I incorporate those discussions fully for this element.

285. The NGC System does not infringe this element because the NGC System does not include "a panel member arranged to separate the fluidics section from the non-fluidics section" as claimed. I incorporate my discussion of elements [1.e] and [1.f] of the '420 patent for this element. In summary, the electronics in the housing are not a separate non-fluidics section from the electronics Dr. Wereley describes as embedded in the panel member. "Embedding" as shown with the arrangement of Bergstrom does not create separate sections. There is no way to square the representations the inventors made about Mourtada, Bergstrom and Hess with respect to separation, with the arrangement in the Bio-Rad accused modules that have electronics adjacent to and on the same side of the panel member as the fluidics. At a minimum, the electronics that Dr. Wereley describes as being embedded in the panel member are the fluidics in the Bio-Rad accused modules, which are not on "either side" of the panel member as the inventors said they must be. Ex. G at 1451 ("The detector module 10 of Fig. 10 illustrates that fluid and electrical parts are adjacent **not on either side of a panel."**)(emphasis added).

2. Element [16.i]: "wherein the liquid handling panel of the housing and the panel members are arranged such that the fluidics sections are external to the housing and respective non fluidics sections are internal to the housing"

286. Element [16.i] requires "wherein the liquid handling panel of the housing and the panel members are arranged such that the fluidics sections are external to the housing and respective non fluidics sections are internal to the housing."

287. The NGC System does not infringe claim 16 at least because it lacks "the liquid handling panel of the housing and the panel members are arranged such that the fluidics sections are external to the housing and respective non fluidics sections are internal to the housing" as claimed.

288. I have discussed why this element is not met with respect to my discussion of elements 1.e and 1.f of the '420 patent. I incorporate those discussions fully for this element.

3. Element [16.j]: "respective non fluidics sections are internal to the housing"

289. Element [16.j] requires that the "respective non fluidics sections are internal to the housing."

290. I have discussed why this element is not met with respect to my discussion of element 1.f of the '420 patent. I incorporate those discussions fully for this element.

4. Dependent Claim 20: "wherein each of the interchangeable modular components includes a dedicated CPU unit allowing each of the interchangeable modular components to independently perform operations in response to instructions over the bus"

291. Element [20.c] requires "wherein each of the interchangeable modular components includes a dedicated CPU unit allowing each of the interchangeable modular components to independently perform operations in response to instructions over the bus."

292. The NGC System does not infringe Claim 20 at least because it lacks "wherein each of the interchangeable modular components includes a dedicated CPU unit allowing each of the interchangeable modular components to independently perform operations in response to instructions over the bus" as claimed.

293. I have discussed why this element is not met with respect to my discussion of element 1.k of the '420 patent. I incorporate those discussions fully for this element.

294. In summary, a person of ordinary skill in the art would not read this limitation to mean that the modular component's cpu does nothing more than take the signal that the master control unit has sent and forward it. For example, if the master control unit sent out a signal that would deliver a certain voltage or current to a module to make it operate at a certain level (*e.g.*, A high or low signal), one of ordinary skill in the art would not read the specification to mean that the CPU would take an instruction and merely create that same current or voltage or simply translate that instruction into a different format.

295. Rather, one of ordinary skill in the art would understand the passage in the specification relating to the use independent operation of the CPU to mean that a signal is received from the master control unit and then the CPU does something above and beyond what that signal indicates and what the MCU would have done on its own, something that is independent of the signal the CPU sent.

5. Dependent Claim 28 "the system includes two double piston pumps, one injection valve for injecting sample onto a column connecting to the flow path of the liquid chromatography system, a UV monitor, and a mixer"

296. Claim 28 depends from claim 16, and further requires that the system recited there comprise "two double piston pumps, one injection valve for injecting sample onto a column connecting to the flow path of the liquid chromatography system, a UV monitor, and a mixer."

297. I have discussed why this element is not met with respect to my discussion of element 1.e of the '420 patent. I incorporate those discussions fully for this element.

6. Dependent Claim 30: "further includes a pH-valve with an integrated flow cell for in-line monitoring of pH levels, and a quaternary valve for automatic buffer preparation and formation of quaternary gradients"

298. Claim 30 depends from claim 28, which in turn depends on claim 16, and requires that the system "further includes a pH-valve with an integrated flow cell for in-line monitoring of

pH levels, and a quaternary valve for automatic buffer preparation and formation of quaternary gradients."

299. I have discussed why this element is not met with respect to my discussion of element 1.e of the '420 patent. I incorporate those discussions fully for this element.

IX. NON-INFRINGING ALTERNATIVES

300. I have also been asked to opine on the existence of non-infringing alternatives and the relative difficult in creating a non infringing alternative by modifying the accused NGC products. In summary, it is my opinion that non-infringing alternatives, such as the Bio-Rad DuoFlow, exist. That chromatography system was the predecessor to the NGC. Moreover, modifications to the NGC could be designed which would avoid infringement.

301. First, with respect to the claims that require the presence of a microprocessor on each individual module that receives instructions from either the master control unit or the system controller and implements instructions independently, there are a number of design options available that would avoid that limitation of the claims. For example, the instructions that the individual who reviewed the source code on Plaintiffs' behalf, Mr. Vukicevic, claims that [redacted] As I explained with respect to the 2040 system, putting a CPU on each module was the result of Moore's law, in which the cost of CPUs became so low that there was no significant different in the cost of placing a CPU on each module or having a shared CPU.

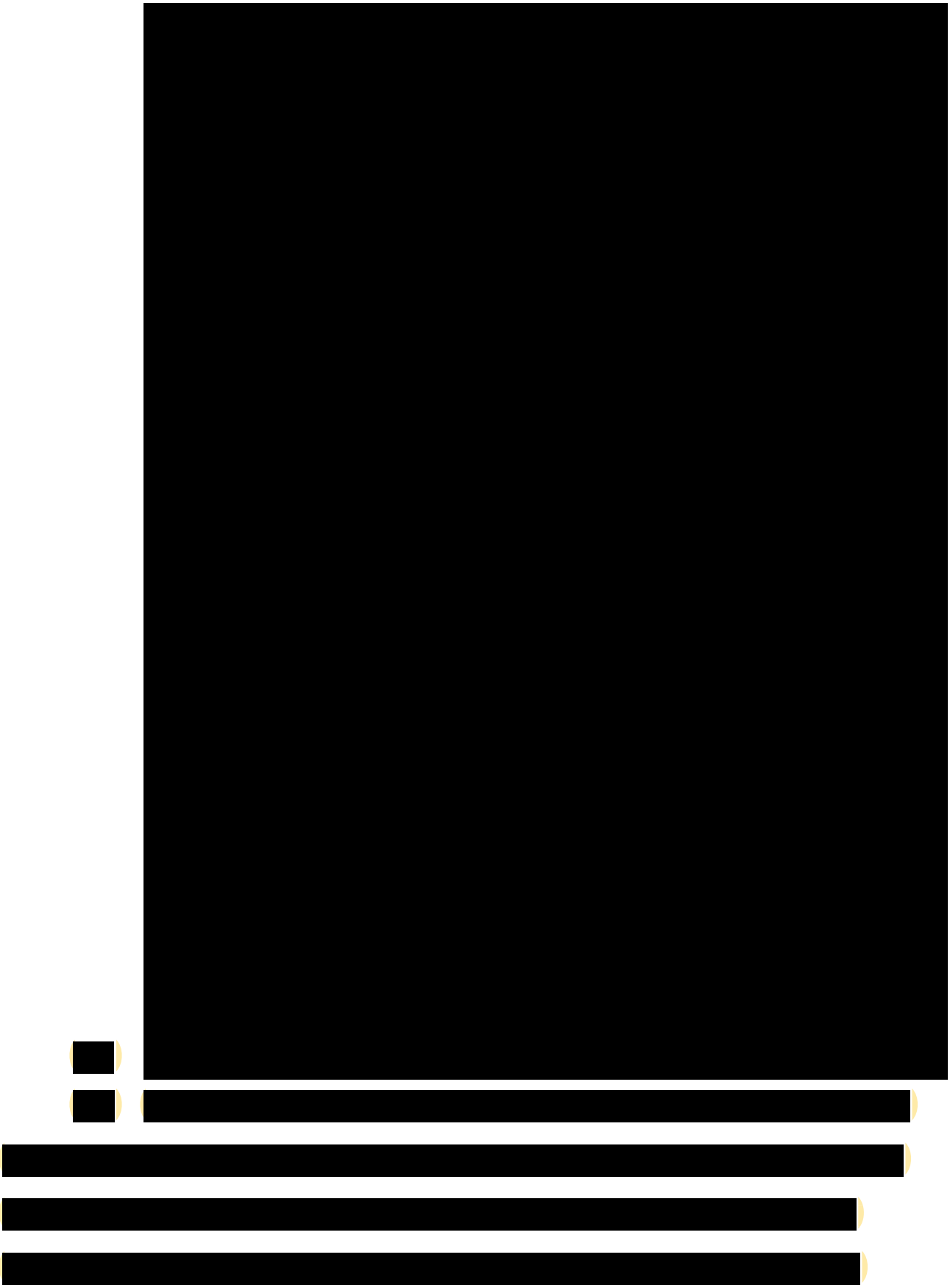
302. In this regard, Dr. Wereley has his analysis backwards. He states that not having a CPU on each module would result in increased cost and complexity and it is not clear that it

comparable and in some cases more advanced than the technology covered by the asserted patents.

[redacted]

[redacted]

[redacted]



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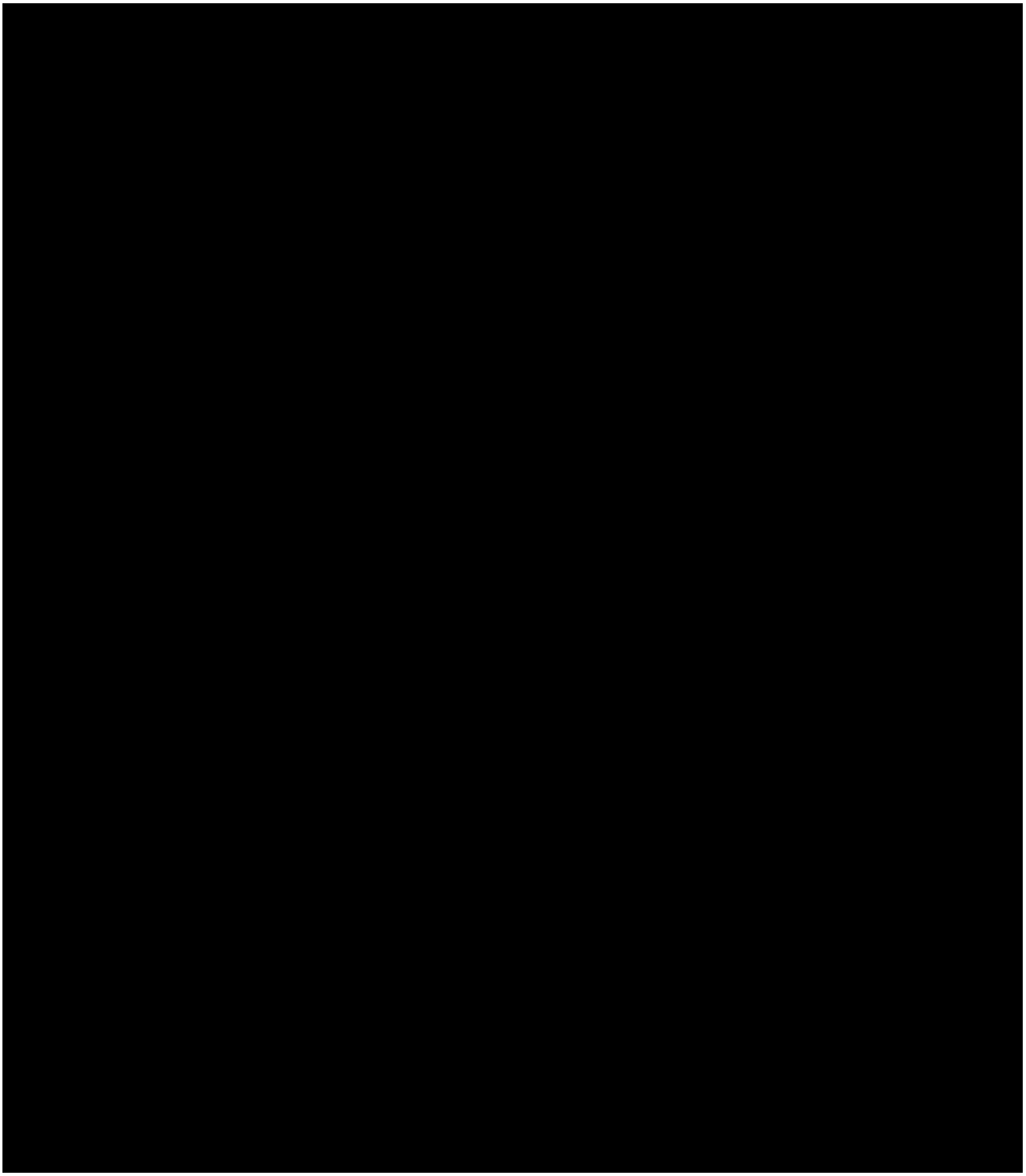

[redacted]

XI. OTHER COMMENTS

348. The opinions expressed in this report are my preliminary opinions based on my review to date of the evidence produced at this stage of the case. I reserve the right to amend or supplement my opinions in light of additional information or materials that may be provided to me or that are relied upon by any of Plaintiffs' experts or witnesses, as well as opinions that Plaintiffs' experts or witnesses may present. I reserve my right to amend or update my opinions

DATED: October 21, 2020

Bruce K. Gale, Ph.D.

EXHIBIT C

US009671420B2

(12) **United States Patent**
Blomberg et al.

(10) **Patent No.: US 9,671,420 B2**
(45) **Date of Patent: *Jun. 6, 2017**

(54) **AUTOMATED FLUID HANDLING SYSTEM**

(71) Applicant: **GE HEALTHCARE BIO-SCIENCES AB**, Uppsala (SE)

(72) Inventors: **Johan Blomberg**, Uppsala (SE); **Mats Lundkvist**, Uppsala (SE)

(73) Assignee: **GE HEALTHCARE BIO-SCIENCES AB**, Uppsala (SE)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **15/261,250**

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(Continued)

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(Continued)

(52) **U.S. Cl.**
CPC ***G01N 35/1097*** (2013.01); ***B01D 15/10*** (2013.01); ***B01D 29/60*** (2013.01);
(Continued)

(58) **Field of Classification Search**
None
See application file for complete search history.

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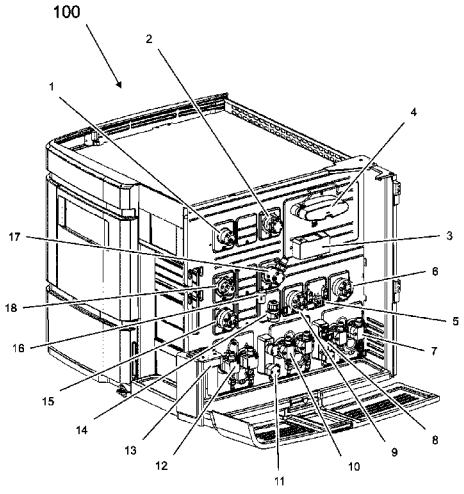
Primary Examiner — Richard Gurtowski
(74) *Attorney, Agent, or Firm* — Arent Fox LLP

(57) **ABSTRACT**

Automated fluid handling system comprising a housing and two or more fluid handling units arranged as interchangeable modular components with an external fluidics section and an internal non fluidics section, and wherein the housing comprises a liquid handling panel with two or more of component positions for receiving said interchangeable modular components such that the external fluidics section is separated from the non fluidics section by the liquid handling panel.

30 Claims, 10 Drawing Sheets



Related U.S. Application Data

No. 14/463,039, filed on Aug. 19, 2014, now Pat. No. 9,404,902, which is a continuation of application No. 13/376,929, filed as application No. PCT/SE2010/050624 on Jun. 4, 2010, now Pat. No. 8,821,718.

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G01N 30/88	(2006.01)
B01D 29/60	(2006.01)
G01N 30/24	(2006.01)
G01N 30/38	(2006.01)
B01D 17/12	(2006.01)
G01N 35/00	(2006.01)
G01N 30/02	(2006.01)

(52) **U.S. Cl.**

CPC ***G01N 30/24*** (2013.01); ***G01N 30/38*** (2013.01); ***G01N 30/88*** (2013.01); *B01D 15/08* (2013.01); *B01D 17/12* (2013.01); *B01D 2201/54* (2013.01); *G01N 2030/027* (2013.01); *G01N 2030/8804* (2013.01); *G01N 2030/8881* (2013.01); *G01N 2035/00326* (2013.01); *Y10T 137/6416* (2015.04); *Y10T 137/6525* (2015.04); *Y10T 137/6851* (2015.04); *Y10T 137/85986* (2015.04); *Y10T 137/87885* (2015.04)

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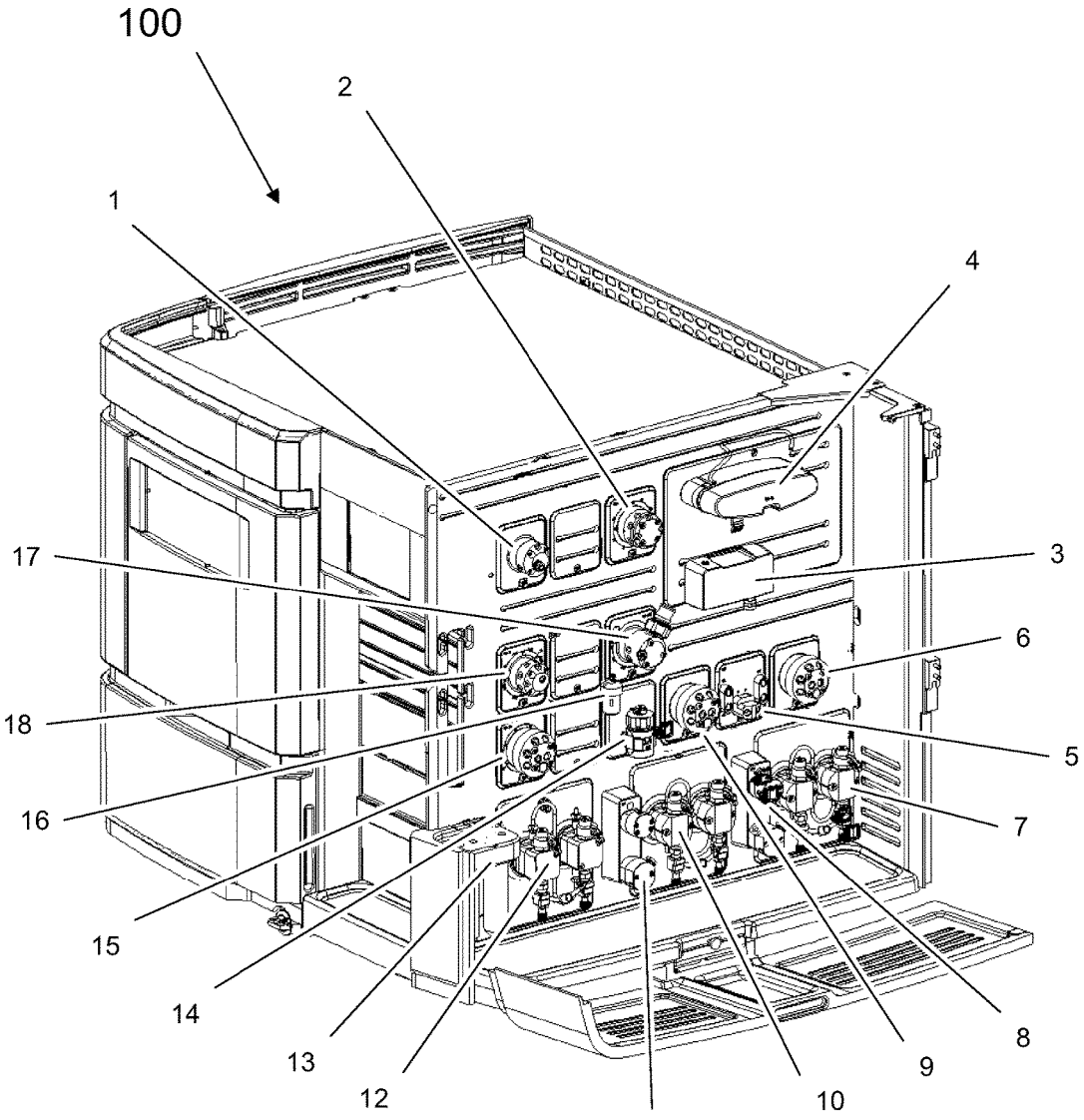
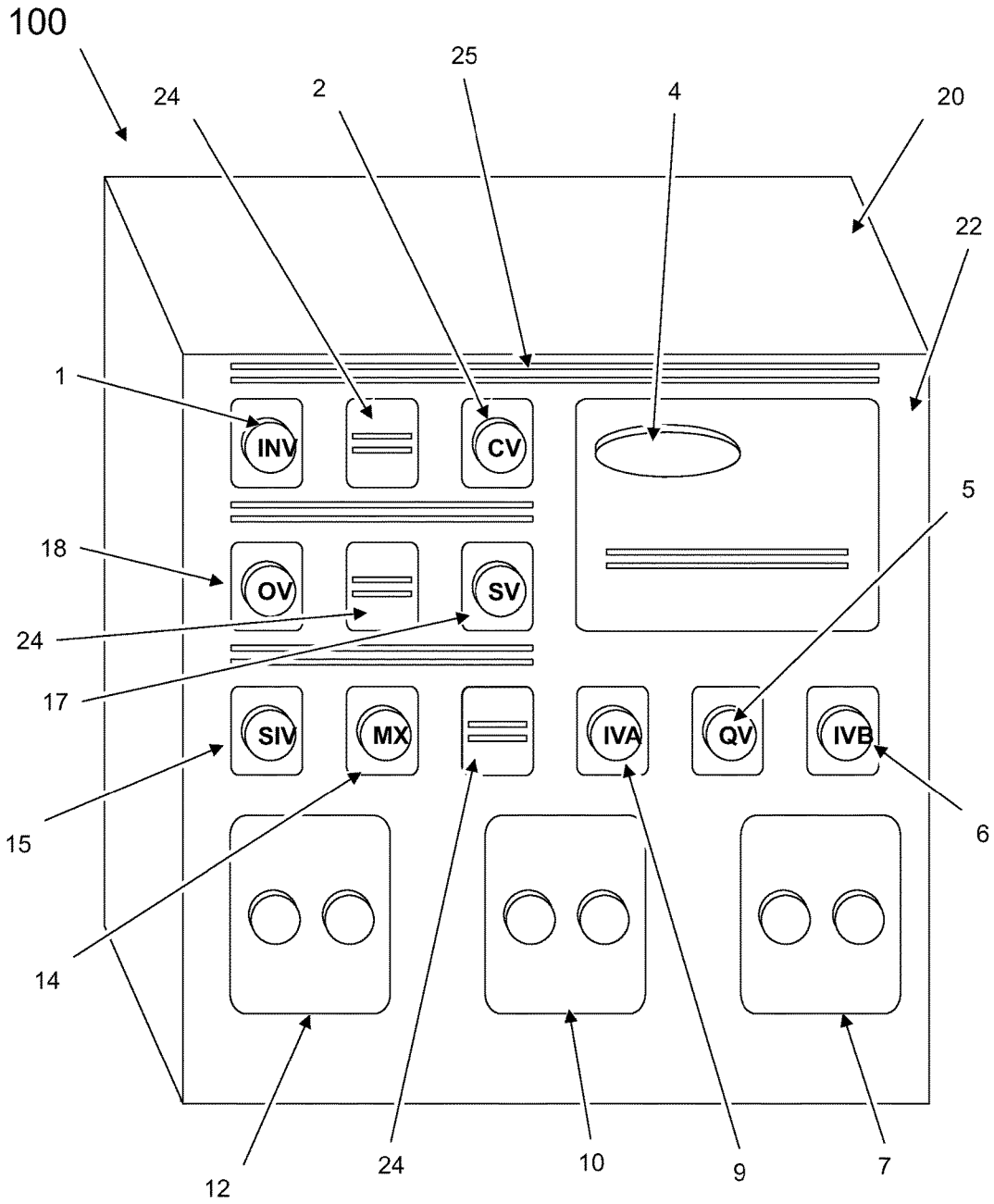


Fig. 1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OV
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IVB
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Fig. 2

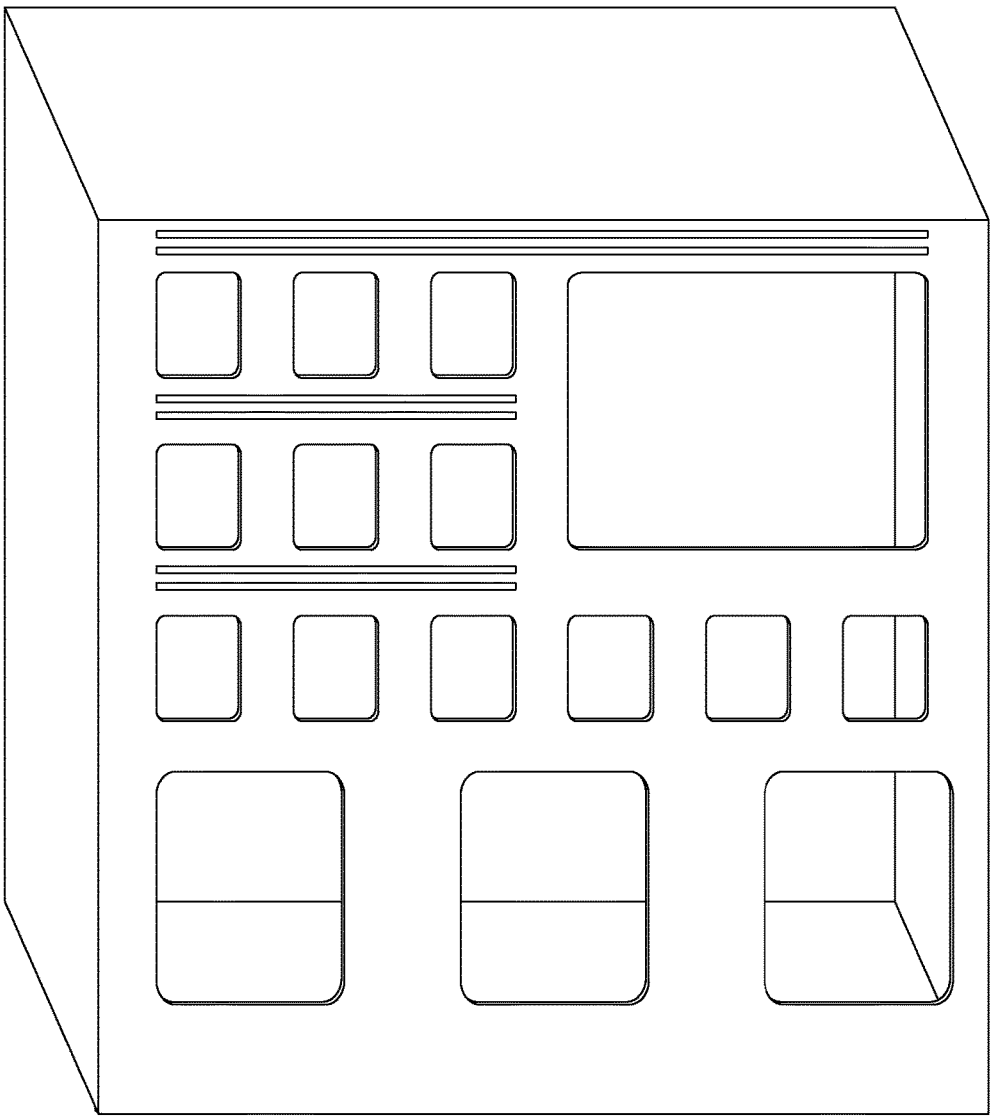


Fig. 3

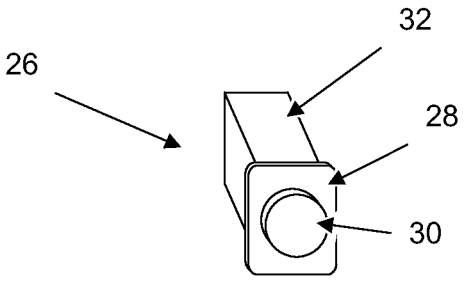


Fig. 4a

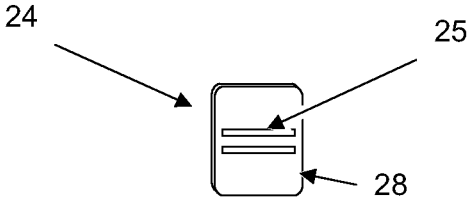


Fig. 4b

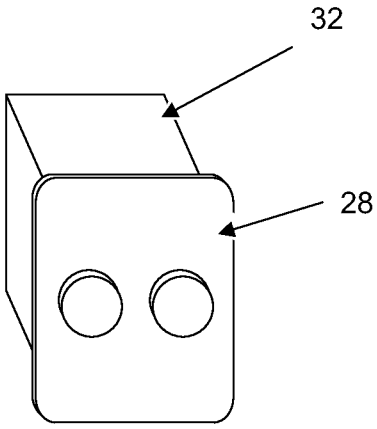


Fig. 4c

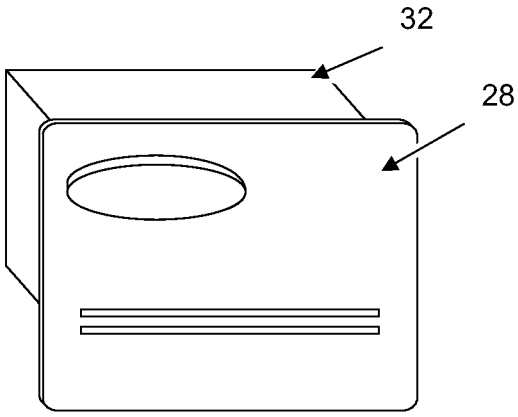


Fig. 4d

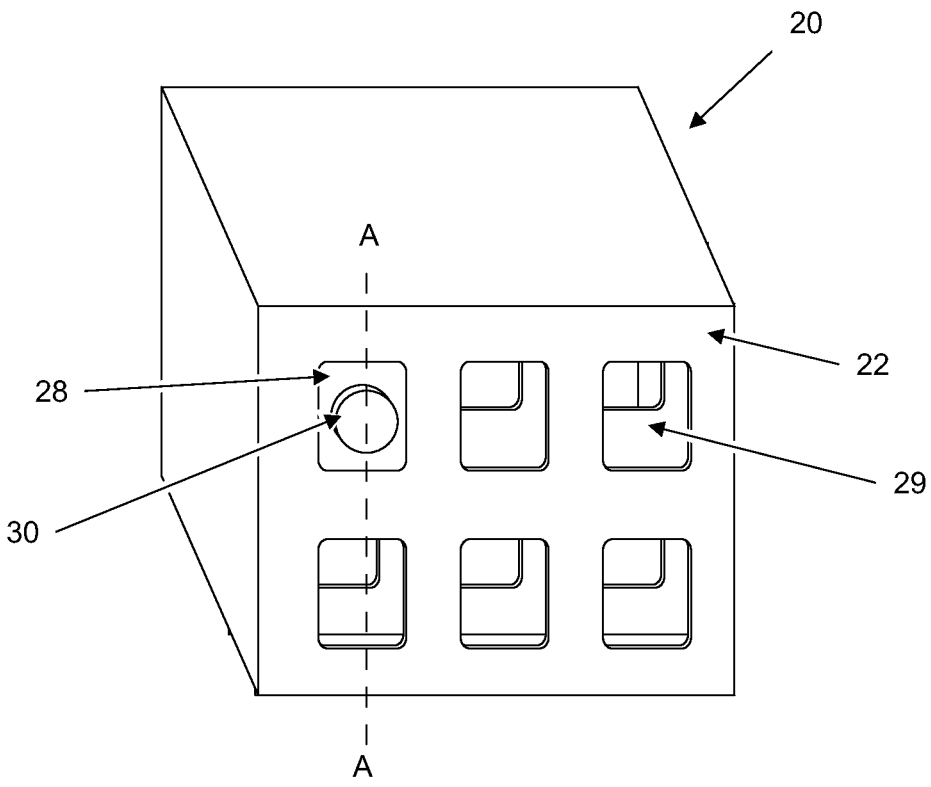


Fig. 5a

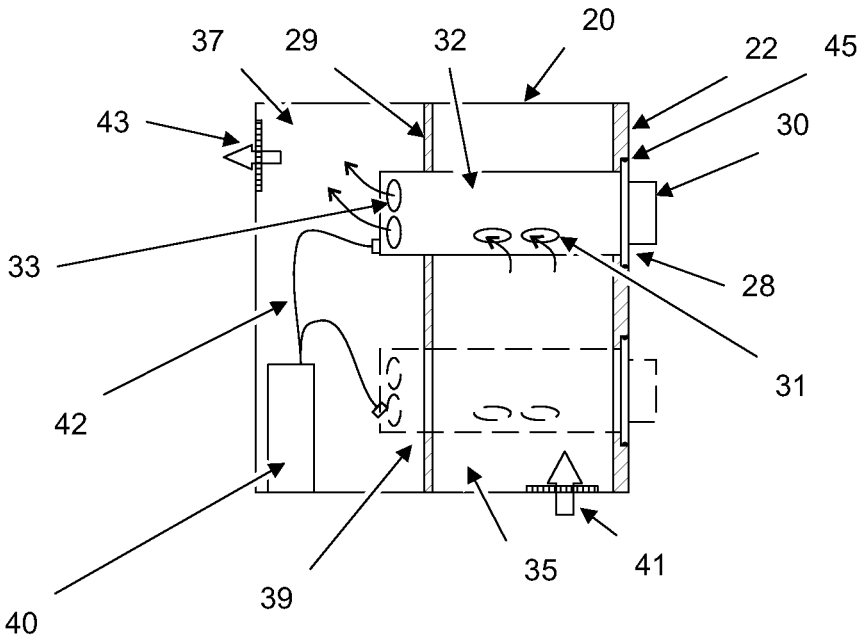


Fig. 5b

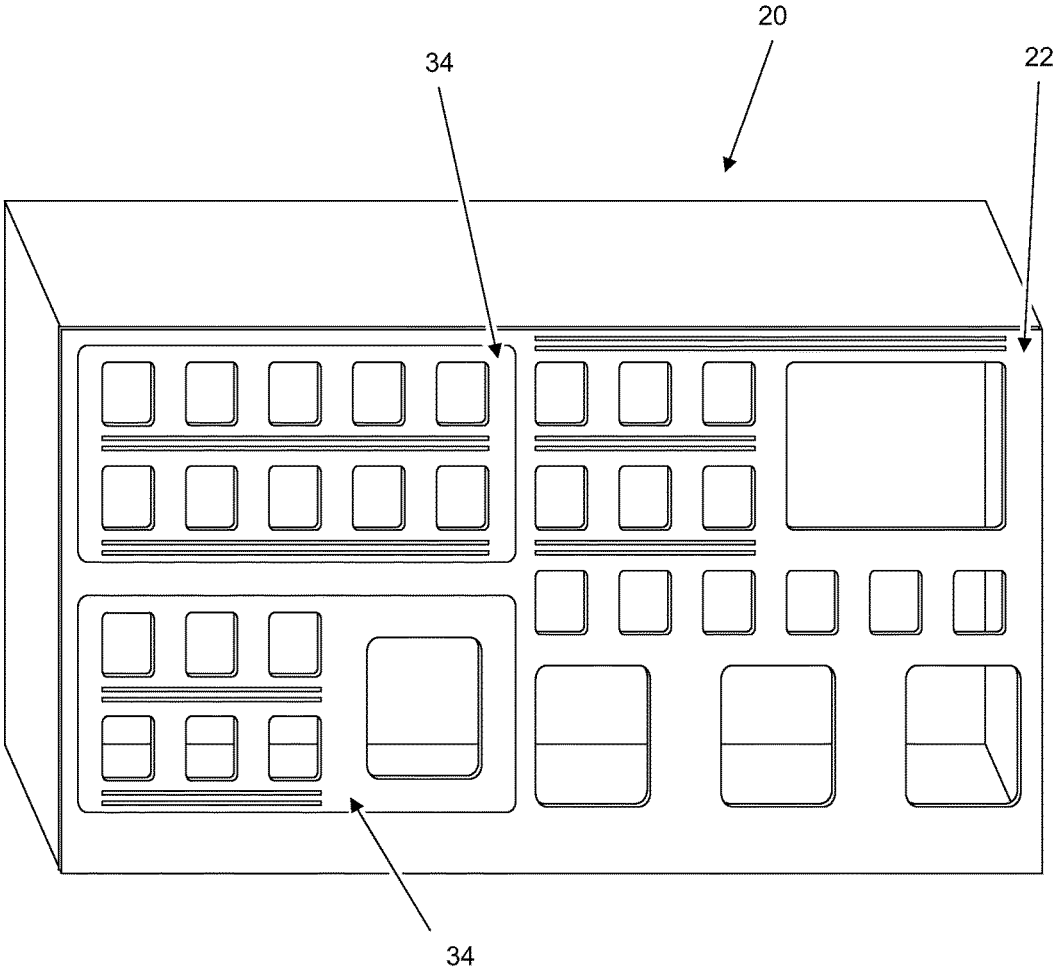


Fig. 6

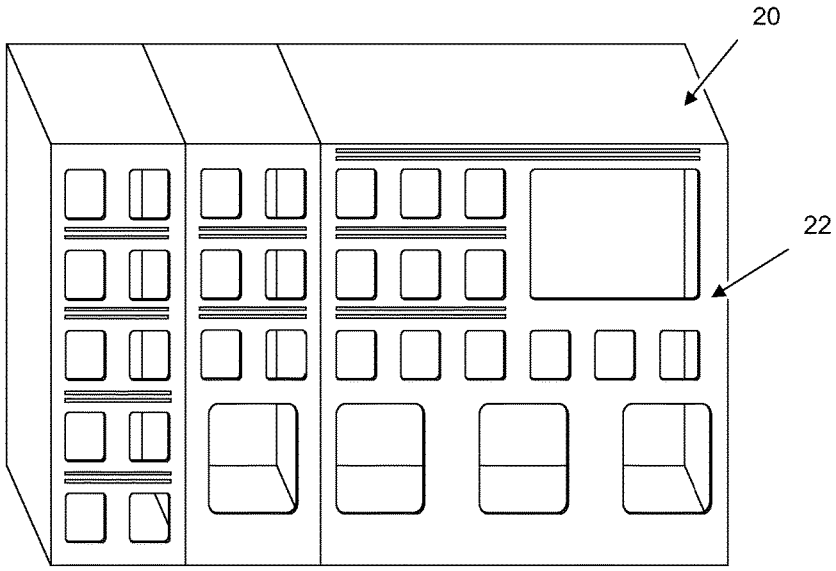


Fig. 7a

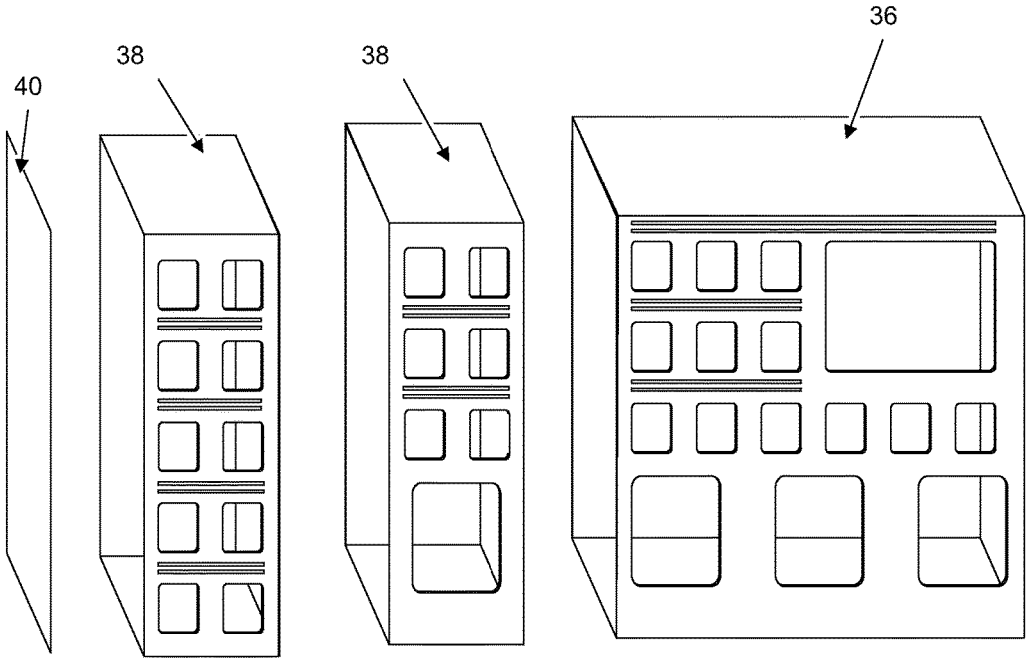


Fig. 7b

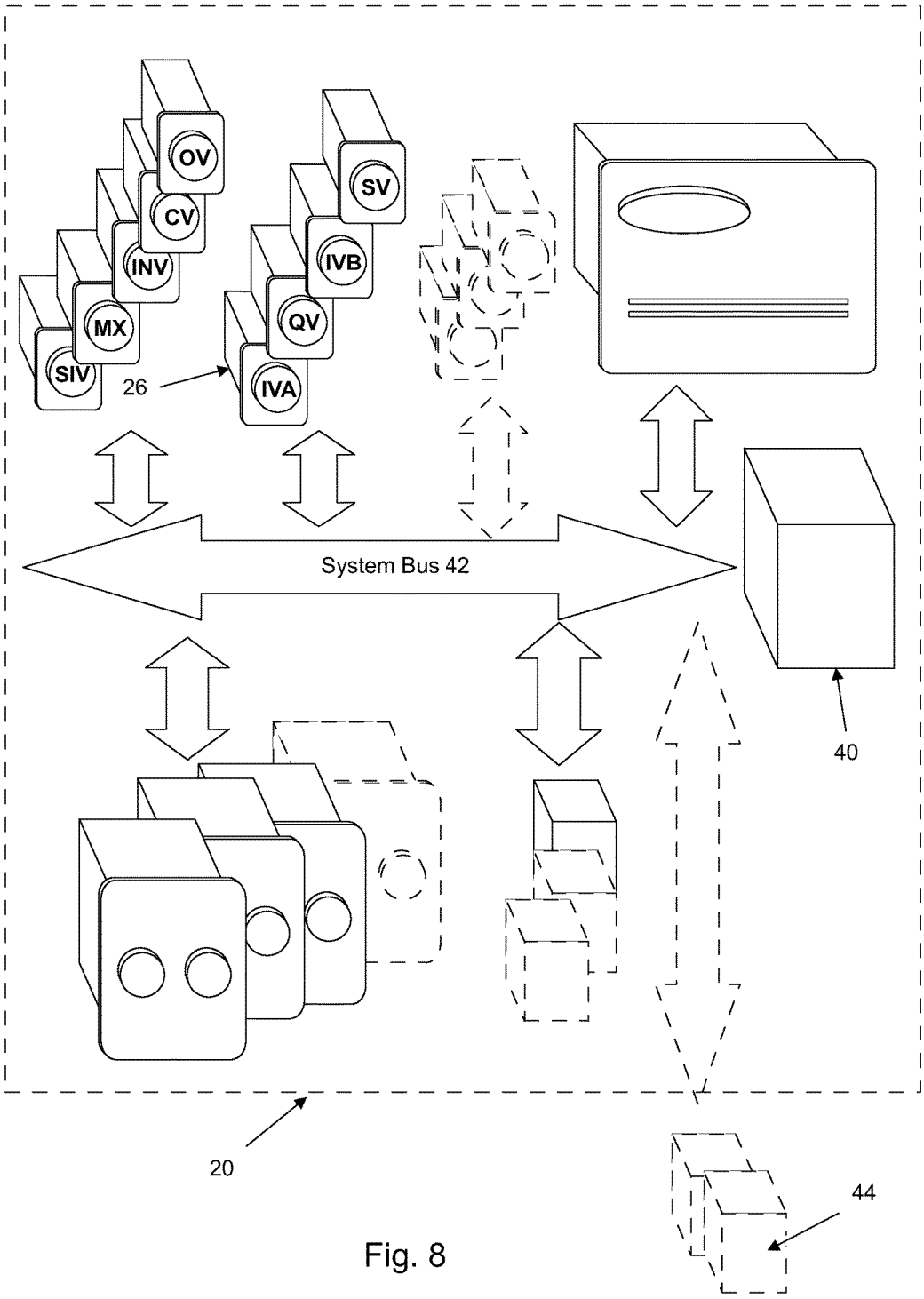
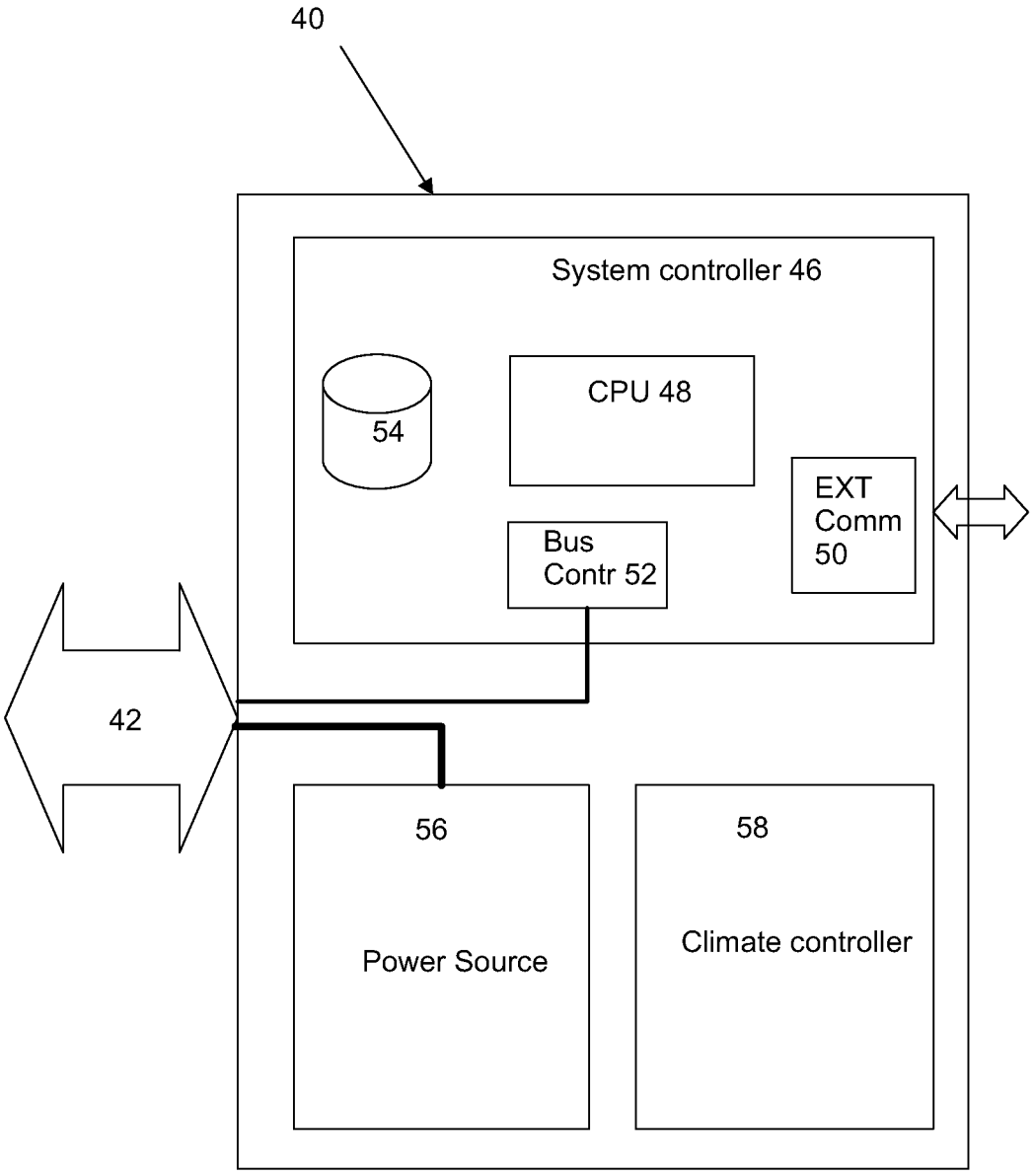


Fig. 8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System controller 46
54
CPU 48
EXT
Comm
50
Bus
Contr 52
42
56
Power Source
58
Climate controller

Fig. 9

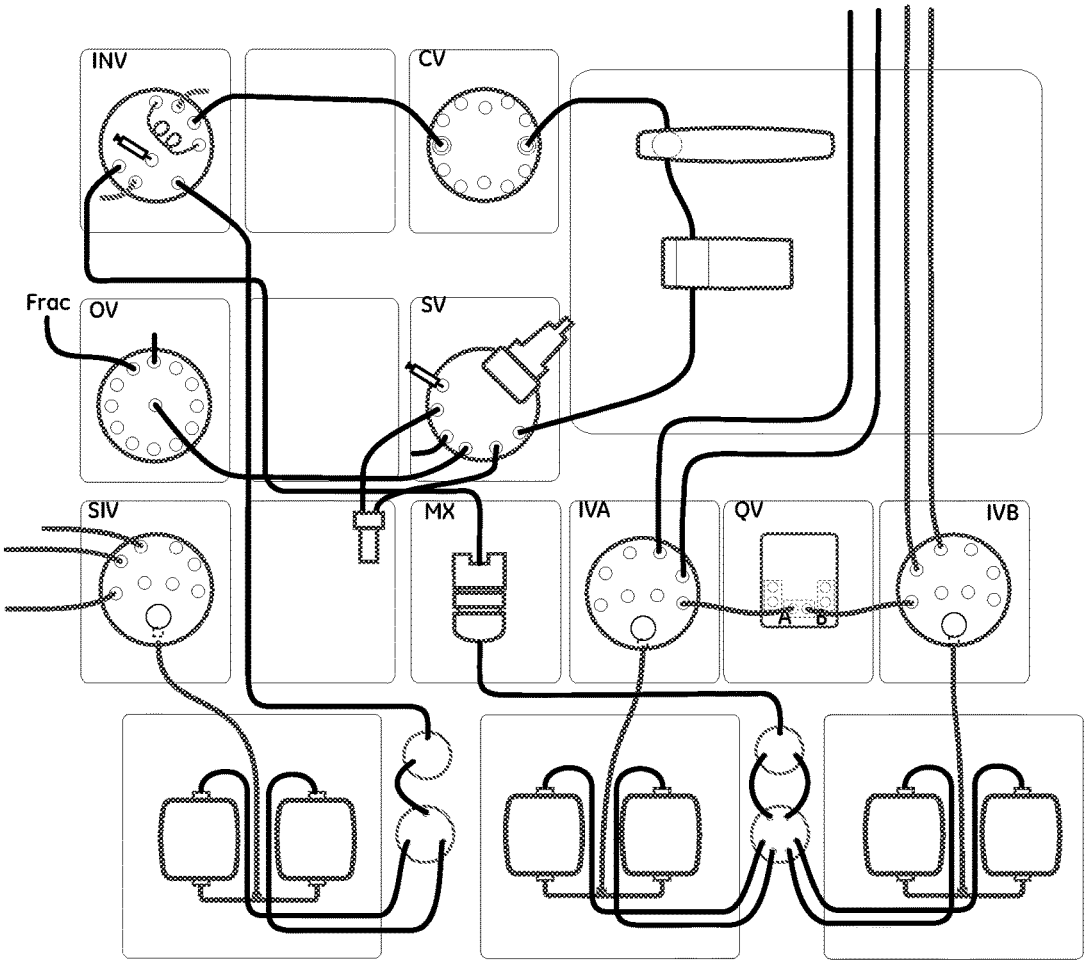

Fig. 10

AUTOMATED FLUID HANDLING SYSTEM

CROSS REFERENCE TO RELATED APPLICATION

This application is a Continuation of U.S. patent application Ser. No. 15/165,876 filed May 26, 2016 which is a Continuation of U.S. patent application Ser. No. 14/463,039 filed Aug. 19, 2014 (now U.S. Pat. No. 9,404,902) which is a Continuation of U.S. patent application Ser. No. 13/376,929 (now U.S. Pat. No. 8,821,718) filed Dec. 8, 2011 which is a 35 U.S.C. §371 National Phase of International Patent Application No. PCT/SE2010/050624 filed Jun. 4, 2010 which claims priority to Swedish Patent Application No. 0950431-7 filed Jun. 9, 2009, the disclosure of these prior applications are hereby incorporated in their entirety by reference

BACKGROUND OF THE INVENTION

The present invention relates to the art of fluid handling system systems, and in particular to an automated fluid handling system that is highly flexible and configurable. The fluid handling system may e.g. be a liquid chromatography system, a filtration system, a chemical synthesis system or the like.

There is a large range of fluid handling systems e.g. in laboratories. Such systems comprise a number of fluid handling units, e.g. one or more pumps, valves, mixers, sensor units etc of different types. Said fluid handling units are interconnected by fluid conduits in the form of, rigid or flexible tubes or the like. Even though some systems may be designed for a specific type of application with a specific flow path, there often exists a need for flexibility and ability to alter or optimize the fluid flow path of the system. Moreover, upgrading is often restricted to specific kits provided by the manufacturer, and upgrade kits often is supplied as external add-on equipment to be arranged besides the original system, thus enlarging the foot print of the system and that need to be connected to the system both fluidically and electrically (i.e. to a system control bus or the like). Moreover, replacement of defect fluid handling units is a time consuming and delicate task.

One type of liquid handling system is liquid chromatography systems which is a standard method in laboratories, and there are a broad range of liquid chromatography systems available on the market. Common to most of the present systems is the lack of flexibility in adapting the instrument to a variety of different applications.

SUMMARY OF THE INVENTION

The object of the invention is to provide a new fluid handling system, which system overcomes one or more drawbacks of the prior art. This is achieved by the fluid handling system as defined in the independent claims.

One advantage with such a fluid handling systems is that the system may easily be upgraded without need for add-on equipment, and that the flow path may be easily optimized for new experimental setups.

Embodiments of the invention are defined in the dependent claims.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be described in detail below with reference to the drawings, in which

FIG. **1** shows one embodiment of a fluid handling system in the form of a liquid chromatography system, according to the present invention.

FIG. **2** is a schematic illustration of a housing with a liquid handling panel of the fluid handling system of FIG. **1**.

FIG. **3** is a schematic illustration of the housing with the liquid handling panel of FIG. **2** with the modular components of the fluid handling system removed.

FIGS. **4***a* to **4***d* are schematic illustrations of examples of component modules of the fluid handling system removed.

FIGS. **5***a* and **5***b* show a schematic embodiment of an automated fluid handling system.

FIG. **6** is a schematic illustration of an embodiment of a housing with a modular liquid handling panel with the modular components of the fluid handling system removed.

FIGS. **7***a* and **7***b* are schematic illustrations of an embodiment of a modular housing with a liquid handling panel with the modular components of the fluid handling system removed.

FIG. **8** is a schematic illustration of an embodiment of the system architecture of one embodiment of a fluid handling system according to the present invention.

FIG. **9** is a schematic illustration of an embodiment of a master control unit of one embodiment of a fluid handling system according to the present invention.

FIG. **10** is a schematic illustration of one embodiment of a fluidic interconnection arrangement between the modular components of the liquid handling panel for the liquid chromatography system of FIG. **1**.

DETAILED DESCRIPTION OF THE INVENTION

According to one embodiment, there is provided an automated fluid handling system comprising a housing and two or more fluid handling units arranged as interchangeable modular components with an external fluidics section and an internal non fluidics section, and wherein the housing comprises a liquid handling panel with two or more of component positions for receiving said interchangeable modular components such that the external fluidics section is separated from the non fluidics section by the liquid handling panel.

According to another embodiment, there is provided a fluid handling system in the form of a liquid chromatography system comprising a housing, two or more high pressure pumps, at least one sensor unit and a plurality of fluid control valves of at least two different configurations, wherein at least the fluid control valves are arranged as interchangeable modular components and the housing comprises a liquid handling panel with a plurality of component positions for receiving said modular components.

FIG. **1** shows one embodiment of an automated fluid handling system modular in the form of a liquid chromatography system, with a plurality of interchangeable modular components arranged in a liquid handling panel wherein the reference numbers denotes:

1. Injection valve
2. Column valve with integrated pressure sensors
3. Conductivity monitor
4. UV monitor
5. Quaternary valve
6. Inlet valve B with integrated air sensor
7. System pump
8. Pressure monitor, system pump
9. Inlet valve A with integrated air sensor
10. System pump

11. Pressure monitor, sample pump
12. Sample pump
13. Rinsing system
14. Mixer with online filter
15. Sample inlet valve with integrated air sensor
16. Flow restrictor
17. pH valve
18. Outlet valve

The disclosed embodiment is supplied with three high precision pumps **7**, **10**, **12**. There are two System pumps **7**, **10**, System pump A **10** and System pump B **7**, and one Sample pump **12**. The System pumps **7**, **10** may be used individually, or in combination to generate isocratic or gradient elution in purification methods. The Sample pump **12** is dedicated for direct loading of sample onto a column, or for filling of sample loops.

Function of the Pumps:

Each pump module consists of two pump heads (not shown). The individual heads are identical but actuated in opposite phase to each other by individual stepper motors, controlled by a microprocessor. The two pistons and pump heads work alternately to give a continuous, low pulsation, liquid delivery. The flow rate of the two System pumps may be varied between about 0.001 ml/min and 25.000 ml/min and the maximum operating pressure is about 20 MPa. The flow rate of the Sample pump may e.g. be varied between 0.01 and 25 ml/min and according to one embodiment the maximum operating pressure is 10 MPa.

According to one embodiment, the plurality of fluid control valves of at least two different configurations are valves of rotary type. Such a motorized rotary valve may consist of a Valve head with a number of defined bores with channels to the inlet and outlet ports of the valve. The Rotary disc, mounted on the motor, has a number of defined channels. The pattern of channels of the Rotary disc together with the pattern and location of the ports of the Valve head, define the flow path and function of each type of valve. When the Rotary disc turns, the flow path in the valve changes.

One embodiment of fluid control valves are Inlet valves A and B (**9**, **6** respectively) that are used to select which buffers or samples to use in a run, and Sample inlet valve **15** that is located before Sample pump **12**. Inlet valve A **9** **1** is located before System pump A **10**, Inlet valve B **6** is located before System pump B **10**, and Sample inlet valve **15** is located before Sample pump **12**. Inlet valve A and Inlet valve B are connected to another embodiment of a fluid control valve in the form of a Quaternary valve **5**. The Quaternary valve is used for automatic buffer preparation, and for formation of quartenary gradients. The number of inlets can be increased by installing component modules with extra inlet valves. Inlet valve A and Inlet valve B enable automatic changing between different buffers and wash solutions, and can be used to generate gradients by mixing buffer A and buffer B. The air sensors integrated in Inlet valve A and Inlet valve B can be used to prevent introduction of air into the pumps and columns.

The Quarternary valve is used for automatic mixing of four different solutions. The Quaternary valve opens one inlet port at a time, and the different solutions are mixed in a Mixer **14** to form the desired buffer. The opening time in the switching valve is controlled by the system. The volume for each inlet port opening increases stepwise when the flow increases. To obtain a homogeneous buffer composition, one has to make sure to use a mixer chamber volume suitable for the flow rate of the method.

The Quaternary valve can be used to create a gradient using four different solutions simultaneously in any combination. The percentage of each solution is controlled by instructions in the method. It is possible to form gradients that changes the percentage of two, three or four solutions linearly over time. This is useful when advanced methods are developed.

The Sample inlet valve **15** enables automatic loading of different samples when using the Sample pump **12** to inject sample directly onto the column or to fill a sample loop. The Sample inlet valve has an inlet dedicated for buffer. This Buffer inlet is used in methods to fill the Sample pump with solution before sample is introduced. The Buffer inlet is also used to wash the Sample pump with buffer between runs. The air sensor integrated in the Sample inlet valve is e.g. used when sample is applied from a vessel onto a column by selecting Inject all sample using air sensor in the Sample application phase of a method. This function uses the Buffer inlet is used to finalize sample injection and to remove air from the Sample pump.

Still another embodiment of fluid control valve may be an Injection valve **1**, which is used to direct sample onto the column. The valve enables usage of a number of different sample application techniques. A sample loop can be connected to the Injection valve and filled either automatically using the Sample pump or manually using a syringe. The sample can also be injected directly onto the column using the Sample pump.

Still another embodiment of fluid control valve may be a Column valve **2** that is used for connection of columns to the system, and to direct the flow onto the column Up to five columns can be connected to the disclosed embodiment of said valve simultaneously. The valve also has a built-in bypass capillary that enables bypassing of connected columns.

The number of column positions can be increased by installing an extra Column valve. Both top and bottom of each column shall be connected to the Column valve. The top of the column shall be connected to one of the A ports (e.g., **1**A), and the bottom of the column shall be connected to the corresponding B port (e.g., **1**B). The flow direction can be set either from the top of the column to the bottom of the column, Down flow, or from the bottom of the column to the top of the column, Up flow. In the default flow path of the Column valve the columns are bypassed. Pressure monitors that measures the actual pressure over the column are integrated into the inlet and outlet ports of the Column valve.

Still another embodiment of fluid control valve may be a pH valve **17** that has an integrated flow cell where a pH electrode can be installed. This enables in-line monitoring of pH during the run. A flow restrictor is connected to the pH valve and can be included in the flow path to generate a backpressure high enough to prevent formation of air bubbles in the UV flow cell. The pH valve is used to direct the flow to the pH electrode and to the flow restrictor, or to bypass one or both.

Still another embodiment of fluid control valve may be an Outlet valve **18** that is used to direct the flow to a Fraction collector (not shown), to any of e.g. 10 outlet ports, or to waste. The number of outlets can be increased by installing an extra Outlet valve.

A Mixer **14** may e.g. be located after System pump A and System pump B and before the Injection valve. The purpose of the Mixer is to make sure that the buffers from the System

pumps are mixed to give a homogenous buffer composition. The Mixer has a built-in filter that prevents impurities from entering the flow path.

To fulfill a desired purpose, with the disclosed liquid chromatography system it is possible to adapt and extend the flow path in a simple and a flexible way. Up to three extra fluid control valves or the like can be installed using the free valve positions. Dummy modules are installed in these positions at delivery. To obtain an optional flow path, it is also possible to move the standard fluid control valves to other positions. There are also two types of extra air sensors available which can be installed before Sample inlet valve or after Injection valve.

In the configuration disclosed in FIG. **1**, 7 inlets are available for each inlet valve. To increase the number of inlets, an extra inlet valve can be installed which increases the number of inlets to 14 for one of the valves. This optional configuration can be convenient for example when a larger number of samples will be used. There is also a general type of inlet valve, Valve X, which can be used to increase the number of inlets to for example the Quaternary valve.

In the configuration disclosed in FIG. **1** with one column valve, 5 column positions are available. To increase the number of column positions to 10, an additional column valve can be installed in the instrument. An application can be to evaluate a number of different columns in method optimization.

In the configuration disclosed in FIG. **1** with one outlet valve, 10 outlet positions are available. To increase the number of outlets, one or two extra outlet valves can be connected, adding up to a total of 21 or 32 outlet positions. This optional configuration is convenient when collecting a number of large fractions outside the fraction collector.

Optional modules are easy to install in the disclosed modular liquid chromatography system. The dummy module is removed with a hexagon wrench and a bus cable is disconnected. The bus cable is connected to the optional fluid control valve or the like which is assembled in the instrument. The module is then added to the System properties in the control software. The available optional modules may e.g. be pre-configured to give the desired function. However, the function of a valve may e.g. be changed by changing the Node ID.

FIG. **2** is a schematic illustration of a housing **20** with a liquid handling panel **22** of the fluid handling system in the form of a modular liquid chromatography system **100** of FIG. **1**. In FIG. **2** some components have been removed for clarity reasons. In the disclosed configuration, as disclosed in detail above, the modular liquid chromatography system **100** comprises a plurality of fluid control valves in the form of: Injection valve **1**, Column valve **2**, Quaternary valve **5**, Inlet valve B **6**, Inlet valve A **9**, Sample inlet valve **15**, pH valve **17**, and Outlet valve **18**. The chromatography system **100** further comprises UV monitor **4**, System pump B **7**, System pump A **10**, Sample pump **12**, Mixer **14**, and three Dummy modules **24**. According to one embodiment, all liquid handling components and sensors arranged at the liquid handling panel **22** are designed to be readily interchangeable. The interchangeability provides improved service and upgrade possibilities and also a possibility to customize the positions of the respective liquid handling components, such as the fluid control valves, e.g. in order to optimize the fluid path for a specific experimental setup. As is illustrated in FIG. **2**, there are three large component positions e.g. for pump modules, one UV-sensor position and 9 standard component positions, e.g. for fluid control valves or the like. The component positions are given a standardized size and shape to provide simple interchangeability. According to one embodiment, each modular component is retained in a mating component position by a single screw, and it is connected to the master control unit by a single bus cable providing both communication and system power to each component. FIG. **3** is a schematic illustration of the housing with the liquid handling panel of FIG. **2** with the modular components of the liquid chromatography system removed.

FIGS. **4***a* to **4***d* are schematic illustrations of examples of fluid handling units in the form of modular component of the fluid handling system removed. FIG. **4***a* shows a standard interchangeable modular component **26**, e.g. a fluid control valve or the like. The standard component module **26** comprises a panel member **28**, an external fluidics section **30** and an internal non-fluidics section **32**. According to one embodiment, the panel member **28** essentially separates the fluidics in the external fluidics section **30** from electronics and control means in the internal non-fluidics section **32**.

FIG. **4***b* shows a Dummy module **24**, which is intended to be placed in non used standard component positions. In the disclosed embodiment, the Dummy modules are provided with mounting grooves for attachment of accessories to the system. In the disclosed embodiment the dummy module is shown as a panel member **28** without any internal section FIGS. **4***c* and **4***d* shows a pump module and an UV-module, respectively, each having an external fluidics section **30** and an internal non-fluidics section **32**.

As is disclosed in FIGS. **4***a* to **4***d*, the interchangeable modular components **26** comprises a panel member arranged to separate the fluidics section from the non fluidics section and for attachment to a component position in the liquid handling panel. Said panel attachment member may be arranged so that all fluid connections of said modular component are arranged on a wet side of the panel attachment member separating them from electrical components that are arranged on a dry side thereof, hence providing a high degree of liquid resistance at the external part of the fluid handling panel, and so that the liquid resistance requirements for the internal sections may be somewhat lightened. According to one embodiment, the interchangeable modular components are sealed against the liquid handling panel by a sealing member. According to another embodiment, not shown, the modular component does not comprise any panel member, but there is provided a suitable sealing arrangement between the component position openings of the liquid handling panel and the external surface of the interchangeable modular components **26**. In the disclosed embodiments, the component position openings of the liquid handling panel and the interchangeable modular components **26** are shown to have an essentially rectangular crosssectional shape, but other shapes may be equally applicable. According to one embodiment, there is provided a general fluid handling system comprising a housing and two or more fluid handling units arranged as interchangeable modular components as is schematically disclosed in FIG. **5***a*. As discussed above such a system may be configured for essentially any type of automated liquid handling operations provided that suitable fluid handling units are provided as interchangeable modular components for the system. According to one embodiment there is provided an automated fluid handling system comprising at least one fluid pump, at least one sensor unit and two or more fluid control valves of at least two different configurations, wherein at least the fluid control valves are arranged as interchangeable modular components.

The liquid handling panel **22** of the fluid handling system may e.g. be designed in any suitable manner to allow the modular components to be arranged in an efficient manner.

FIGS. **5***a* and **5***b* shows a schematic embodiment of an automated fluid handling system wherein the housing **20** comprises an internal climate panel **29** arranged at a distance behind the liquid handling panel **22** defining an air inlet compartment **35** and air outlet compartment **37** in the housing **20**, the climate panel **29** being provided with complementary component positions **39** for receiving the internal non fluidics section **32** of the interchangeable modular components **26**, and wherein the non-fluidics section **32** of at least one interchangeable modular component is provided with one or more air inlet openings **31** located in the air inlet compartment **35** and one or more air outlet openings **33** located in the air outlet compartment **37** when the interchangeable modular component arranged in position in the component position. FIG. **5***b* shows the fluid handling system of FIG. **5***a* in a schematic cross sectional view. As is indicated by inlet vent **41** and outlet vent **43**, air for cooling interchangeable modular components **26** provided with air inlet and outlet openings **31**, **33** is preferably arranged to enter the air inlet compartment **35** at a distance from the outlet vent **43** in order to avoid recirculation of air. The air circulation in the system may be achieved by a system cooling unit (not shown) providing a flow of air from the air inlet compartment **35** to the air outlet compartment **37**, through the at least one interchangeable modular component **26**. Alternatively, the at least one interchangeable modular component **26** is provided with a local cooling unit (not shown) providing a flow of air from the air inlet compartment **35** to the air outlet compartment **37**. As is indicated, the complementary component positions **39** are arranged to provide a relatively air flow tight fit with respect to the internal non fluidics section **32** of the interchangeable modular components **26**, and according to one embodiment, this may be achieved by a sealing arrangement. In FIG. **5***b*, there is shown a sealing member **45** for sealing the interchangeable modular components **26** with respect to the liquid handling panel **22**, as discussed above. Other sealing member arrangements may be envisaged by a person skilled in the art. According to one embodiment, fluids are strictly restricted to the fluidics section **30** of the interchangeable modular component **26**, but in alternative embodiments, only fluid connections are restricted to the fluidics section **30** allowing fluid to "cross" the fluid handling panel inside the non-fluidics section **30** of the interchangeable modular component **26**.

In FIG. **5***b* there is further shown a master control unit **40** and buss connectors **42** for connecting the interchangeable modular components **26** to the master control unit **40**. According to one embodiment, the component positions including the buss connectors **42** and the interchangeable modular components **26** are of plug and play configuration with respect to each other.

FIG. **6** is a schematic illustration of an embodiment of a housing **20** with a modular liquid handling panel **22** with the modular components of the liquid chromatography system removed. In the disclosed embodiment, also the layout of the liquid handling panel **22** is configurable by means of two interchangeable panel sections **34** which may be selected in accordance with the desired layout of the system. In FIG. **6** two different layouts of the interchangeable panel sections are disclosed, but the layout may include any suitable configuration.

FIGS. **7***a* and **7***b* are schematic illustrations of an embodiment of a modular housing with a liquid handling panel with the modular components of the liquid chromatography system removed. In the disclosed embodiment, the modular housing is comprised of a main housing **36** that comprises the master control unit including power supply and climate control for the whole housing, two expansion housing modules **38** and a side member **40**. This approach provides very flexible expansion possibilities for the chromatography system, while preserving the benefits of a single master control unit including power supply and climate control.

FIG. **8** is a schematic illustration of an embodiment of the system architecture of one embodiment of a modular liquid chromatography system according to the present invention. As mentioned above, the chromatography system may comprise a master control unit **40** arranged to communicate with all modular components e.g. **1**-**26**, over a system bus **42** such as a CAN-bus or the like. In one embodiment, each modular component is provided with a dedicated CPU unit allowing the component to independently perform operations in response to instructions over the BUS **42**. In order to minimize the number of connectors to be attached to each modular component, the bus **42** further comprises power feed for the modular components. The Bus **42** may be connected to any suitable number of modular components arranged in the housing **20**, but also to one or more modular components **44** outside of the housing **20** or the like. As is mentioned briefly above, the master control unit may further be arranged to control the climate in the housing. In addition to the disclosed modular components, other components of the chromatography system, e.g. a fraction collector or the like, may be arranged in the housing and the controlled climate therein.

According to one embodiment, different component modules are automatically identified by the master control unit, whereby they may be moved essentially freely between different positions. Moreover, the master control unit may be arranged to provide said information to Chromatography control software whereby experimental setup and planning may be performed. In one embodiment, the control system may be arranged to provide an optimized layout of the component modules with respect to the present layout of the liquid handling panel and available component modules for a specific experimental setup.

According to one embodiment, the interchangeable panel sections **34** of FIG. **5** and the expansion housing modules **38** of FIGS. **6***a* and **6***b* may be provided with means for automatic detection of the same to allow automatic configuration of the system by the master control unit **40**. In one embodiment, each interchangeable panel section **34** and expansion housing module **38** comprises a hub (not shown) for connection to the system bus **42** in order to expand the system bus **42** network to the number of component modules in each interchangeable panel section **34** or expansion housing module **38**.

FIG. **9** is a schematic illustration of an embodiment of a master control unit of one embodiment of a modular liquid chromatography system according to the present invention. The master control unit **40** comprises a system controller **46** for communicating with internal and external components and control computers (not shown) etc. According to one embodiment, the system controller comprises a suitable CPU **48**, a bus controller **52**, an external communications controller **50**, such as a LAN unit, and a storage device **54**. The bus controller **52** is providing communication with the component modules. The master control unit may further comprise a Power supply **56** and a climate controller **58** arranged to keep the internal climate in the housing **20** at a predetermined level as discussed above.

FIG. **10** is a schematic illustration of one embodiment of a fluidic interconnection arrangement between the modular components of the liquid handling panel. Taking into account the complexity of the disclosed interconnection arrangement, the benefit of optimizing the fluid paths in alternative configurations of the system becomes evident. The task of optimizing the fluid paths may e.g. be performed to reduce the total length/volume of the fluid paths/tubing arranged to interconnect the different component modules in the system. Alternatively the optimization may be performed to minimize the length/volume of one or more specific fluid paths, such as the sample output path from the column to the fraction collector, in order to minimize dispersion of the fractionized sample.

The invention claimed is:

1. An automated liquid chromatography system comprising:

a housing;

a master control unit connected to a system bus; and

three or more fluid handling units arranged as interchangeable modular components comprising (i) an external fluidics section, (ii) an internal non-fluidics section including a bus connector for directly connecting the interchangeable modular component with the system bus, and (iii) a panel member arranged to separate the fluidics section from the non-fluidics section;

wherein the housing comprises a liquid handling panel with at least four component receiving positions arranged in a two dimensional array and adapted to receive said interchangeable modular components such that, when inserted, the fluidics section is external to the housing and the non-fluidics section is internal to the housing;

wherein each component receiving position includes a complementary connector for connecting the bus connector of the interchangeable modular component inserted therein to said system bus;

wherein each interchangeable modular component includes a dedicated CPU unit allowing the interchangeable modular component to independently perform operations in response to instructions over the system bus;

wherein the master control unit is arranged to automatically identify interchangeable modular components;

wherein said housing is adapted to accommodate at least one pump, at least one sensor unit and at least two fluid control valves of different configurations, of which at least three of the pump, the sensor unit, and the fluid control valves are interchangeable modular components; and

wherein the system is capable of performing automated liquid chromatography.

2. The chromatography system of claim **1**, wherein the interchangeable modular components are sealed against the liquid handling panel by a sealing member.

3. The chromatography system of claim **1**, wherein the interchangeable modular components are all of the same size.

4. The chromatography system of claim **1**, wherein the interchangeable modular components are of two or more sizes.

5. The chromatography system of claim **1**, wherein the liquid chromatography system further comprises a pH electrode that is external to the housing.

6. The chromatography system according to claim **5**, wherein the at least two fluid control valves include an injection valve, a column valve with integrated pressure sensors, a quaternary valve, an inlet valve, a sample inlet valve, a pH valve, or an outlet valve.

7. The chromatography system according to claim **5**, wherein the pH electrode is connected to a pH valve formed as an interchangeable modular component.

8. The chromatography system according to claim **7**, wherein the pH valve includes an integrated flow cell for in-line monitoring of pH levels.

9. The chromatography system of claim **1**, wherein the liquid chromatography system further comprises at least one expansion housing module arranged to be attached to the housing and for accommodating additional interchangeable modular components.

10. The chromatography system of claim **1**, wherein the liquid chromatography system comprises two double piston pumps, one injection valve for injecting sample onto a column connecting a flow path of the liquid chromatography system, a UV monitor, and a mixer, wherein the pumps, valve, monitor, and mixer are interchangeable modular components.

11. The chromatography system of claim **10**, wherein the liquid chromatography system further comprises a column valve comprising pressure sensors integrated into inlet and outlet ports of the column valve for measuring the actual pressure over the connected column.

12. The chromatography system of claim **10**, wherein the liquid chromatography system further comprises a sample inlet valve.

13. The chromatography system of claim **10**, wherein the liquid chromatography system further comprises a conductivity monitor.

14. The chromatography system of claim **10**, wherein the liquid chromatography system further comprises at least one expansion housing module arranged to be attached to the housing and for accommodating additional interchangeable modular components.

15. The chromatography system according to claim **1**, wherein the at least two fluid control valves include an injection valve, a column valve with integrated pressure sensors, a quaternary valve, an inlet valve, a sample inlet valve, a pH valve, or an outlet valve.

16. The chromatography system of claim **1**, wherein the liquid chromatography system includes two double piston pumps, one injection valve for injecting a sample onto a column connected to a flow path of the liquid chromatography system, a UV monitor, a mixer, a pH-valve with an integrated flow cell for in-line monitoring of pH levels, and a quaternary valve for automatic buffer preparation and formation of quaternary gradients, wherein the pumps, injection valve, monitor, mixer, pH valve, and quaternary valve are interchangeable modular components.

17. An automated liquid chromatography system comprising:

a housing;

a master control unit connected to a system bus; and

two or more fluid handling units arranged as interchangeable modular components comprising a panel member arranged to separate a fluidics section from a non-fluidics section, wherein the fluidics section of each interchangeable modular component comprises one or more fluid connectors for connecting the fluid handling unit to a liquid chromatography fluid path and wherein all fluid connectors are on an external side of the panel member, said liquid chromatography fluid path being reconfigurable by moving the interchangeable modular components freely between the component receiving

positions, and wherein the non-fluidics section includes a bus connector for directly connecting the interchangeable modular components to the system bus;

wherein the housing comprises a liquid handling panel with two or more component receiving positions adapted to receive said interchangeable modular components such that, when inserted, the fluidics section is external to the housing and the non-fluidics section is internal to the housing;

wherein each component receiving position includes a complementary connector for connecting the bus connector of the interchangeable modular component inserted therein to said system bus;

wherein each interchangeable modular component includes a dedicated CPU unit allowing the interchangeable modular component to independently perform operations in response to instructions over the system bus;

wherein the master control unit is arranged to automatically identify interchangeable modular components;

wherein said housing is adapted to accommodate at least one pump, at least one sensor unit and at least two fluid control valves of different configurations, of which at least two of the pump, the sensor unit, and the fluid control valves are interchangeable modular components; and

wherein the system is capable of performing automated liquid chromatography.

18. The chromatography system of claim **17**, wherein the interchangeable modular components are all of the same size.

19. The chromatography system of claim **17**, wherein the interchangeable modular components are of two or more sizes.

20. The chromatography system of claim **17**, wherein the two or more component receiving positions are arranged in a two dimensional array.

21. The chromatography system of claim **17**, wherein the housing comprises at least four component receiving positions.

22. The chromatography system of claim **17**, wherein the liquid chromatograph system further comprises a pH electrode that is external to the housing.

23. The chromatography system according to claim **22**, wherein the at least two fluid control valves include an injection valve, a column valve with integrated pressure sensors, a quaternary valve, an inlet valve, a sample inlet valve, a pH valve, or an outlet valve.

24. The chromatography system according to claim **22**, wherein the pH electrode is connected to a pH valve formed as an interchangeable modular component.

25. The chromatography system according to claim **24**, wherein the pH valve includes an integrated flow cell for in-line monitoring of pH levels.

26. The chromatography system of claim **17**, wherein the liquid chromatography system further comprises at least one expansion housing module arranged to be attached to the housing and for accommodating additional interchangeable modular components.

27. An automated liquid chromatography system comprising:

a housing;

a master control unit connected to a system bus; and

two or more fluid handling units arranged as interchangeable modular components comprising a panel member arranged to separate a fluidics section from a non-fluidics section, wherein the fluidics section of each interchangeable modular component comprises one or more fluid connectors for connecting the fluid handling unit to a liquid chromatography fluid path and wherein all fluid connectors are on an external side of the panel member, said liquid chromatography fluid path being reconfigurable by moving the interchangeable modular components freely between the component receiving positions, and wherein the non-fluidics section includes a bus connector for directly connecting the interchangeable modular components to the system bus;

wherein the housing comprises a liquid handling panel with at least four component receiving positions arranged in a two dimensional array and adapted to receive said interchangeable modular components such that, when inserted, the fluidics section is external to the housing and the non-fluidics section is internal to the housing;

wherein each component receiving position includes a complementary connector for connecting the bus connector of the interchangeable modular component inserted therein to said system bus;

wherein each interchangeable modular component includes a dedicated CPU unit allowing the interchangeable modular component to independently perform operations in response to instructions over the system bus;

wherein the master control unit is arranged to automatically identify interchangeable modular components;

wherein said housing is adapted to accommodate at least one pump, at least one sensor unit and at least two fluid control valves of different configurations, of which at least two of the pump, the sensor unit, and the fluid control valves are interchangeable modular components; and

wherein the system is capable of performing automated liquid chromatography.

28. The chromatography system of claim **27**, wherein the interchangeable modular components are all of the same size; or of two or more sizes.

29. The chromatography system of claim **27**, wherein the system further comprises at least one expansion housing module arranged to be attached to the housing and for accommodating additional interchangeable modular components.

30. The chromatography system of claim **27**, wherein the system further comprises a pH electrode that is external to the housing, and wherein the pH electrode is connected to a pH valve formed as an interchangeable modular component.

* * * * *

EXHIBIT D

Trials@uspto.gov
571-272-7822

Paper 39
Entered: February 6, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIO-RAD LABORATORIES, INC.,
Petitioner,

v.

GE HEALTHCARE BIO-SCIENCES AB,
Patent Owner.

Case IPR2015-01826
Patent 8,821,718 B2

Before GRACE KARAFFA OBERMANN, JO-ANNE M. KOKOSKI, and MICHELLE N. ANKENBRAND, *Administrative Patent Judges.*

ANKENBRAND, *Administrative Patent Judge.*

FINAL WRITTEN DECISION
Determining Claims 1–3 and 5 Unpatentable
35 U.S.C. § 318(a); 37 C.F.R. § 42.73
Dismissing as Moot Patent Owner's Motion to Exclude
37 C.F.R. 42.64(c)

I. INTRODUCTION

This is a Final Written Decision in an *inter partes* review challenging the patentability of claims 1–3 and 5 ("the challenged claims") of U.S. Patent No. 8,821,718 B2 (Ex. 1001, "the '718 patent"). We have jurisdiction under 35 U.S.C. § 6. For the reasons that follow, we determine Petitioner demonstrates, by a preponderance of evidence, that claims 1–3 and 5 are unpatentable.

A. Procedural History

Bio-Rad Laboratories, Inc. ("Petitioner") filed a Petition (Paper 2, "Pet.") for *inter partes* review pursuant to 35 U.S.C. § 311. On February 29, 2016, we instituted trial on three grounds of unpatentability asserted in the Petition:

(1) Whether claims 1–3 and 5 of the '718 patent are unpatentable under 35 U.S.C. § 102 as anticipated by the 2040 Manual;[1]

(2) Whether claim 3 of the '718 patent is unpatentable under 35 U.S.C. § 103 as obvious over the 2040 Manual; and

(3) Whether claim 1 of the '718 patent is unpatentable under 35 U.S.C. § 102 as anticipated by the Gilson 402 User Guide.[2]

Paper 11 ("Institution Decision" or "Inst. Dec.").

GE Healthcare Biosciences AB ("Patent Owner") filed a Response (Paper 23, "Resp."), and Petitioner filed a Reply (Paper 28, "Reply").

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[1] Applikon Analytical B.V., ADI 2040 Process Analyzer Manual (Ex. 1002, "2040 Manual").

[2] Gilson 402 Syringe Pump User's Guide, *available at* http://web.archive.org/web/20031115192306/http:/www.gilson.com/Products/prodPDF.asp?pID=17&pdftid=USER (Ex. 1011, "Gilson 402 User Guide").

Petitioner supports its Petition with the Declaration of Dr. Bruce Gale (Ex. 1018). Patent Owner relies on the Declaration of Mats Söderman (Ex. 2009).

Patent Owner's fully briefed Motion to Exclude also is pending. Paper 32 (Motion); Paper 36 (Petitioner's Response); Paper 37 (Patent Owner's Reply). The record further includes a transcript of the final oral hearing conducted on November 17, 2016. Paper 38 ("Tr.").

B. Related Proceedings

The parties indicate that the '718 patent is the subject of a concurrent proceeding in the United States District Court for the Southern District of New York: *GE Healthcare Bio-Sciences AB v. Bio-Rad Laboratories, Inc.*, Case No. 1:14-cv-07080-LTS-SN (S.D.N.Y.), which has been stayed. Pet. 1; Paper 10, 1. The '718 patent also is the subject of a reissue proceeding, U.S. Patent Reissue Application No. 15/008,155 (filed January 27, 2016), which the Board stayed pending the completion of this proceeding. Paper 10, 1; *see* Paper 18.

C. The '718 Patent

The '718 patent, titled "Automated Fluid Handling System," issued on September 2, 2014. The '718 patent relates to "an automated fluid handling system that is highly flexible and configurable." Ex. 1001, 1:15–16. The fluid handling system may be, *inter alia*, a liquid chromatography system comprising a number of fluid handling units, including pumps, valves, mixers, and sensor units. *Id.* at 1:16–18. According to the specification, although fluid handling systems are known in the art, most of the conventional systems lack flexibility, such that the systems cannot be configured for a variety of different applications and replacing defective

components (i.e., fluid handling units) is "a time consuming and delicate task." *Id.* at 1:19–41. In addition, conventional systems require specific kits for upgrading that are supplied as external add-on equipment and arranged beside the original system, thereby enlarging the system's footprint. *Id.* at 1:27–33.

According to one embodiment, the fluid handling system comprises housing 20 and two or more fluid handling units 26 arranged as interchangeable modular components with external fluidics section 30 and internal non fluidics section 32, wherein housing 20 comprises liquid handling panel 22 with two or more component positions for receiving said interchangeable modular components such that external fluidics section 30 is separated from internal non fluidics section 32 by panel member 28 attached to liquid handling panel 22. *Id.* at Abstract, 2:23–31, Figs. 2–4a. According to another embodiment, the fluid handling system is in the form of a liquid chromatography system. *Id.* at 2:32–63. Figure 2 of the '718 patent is reproduced below.

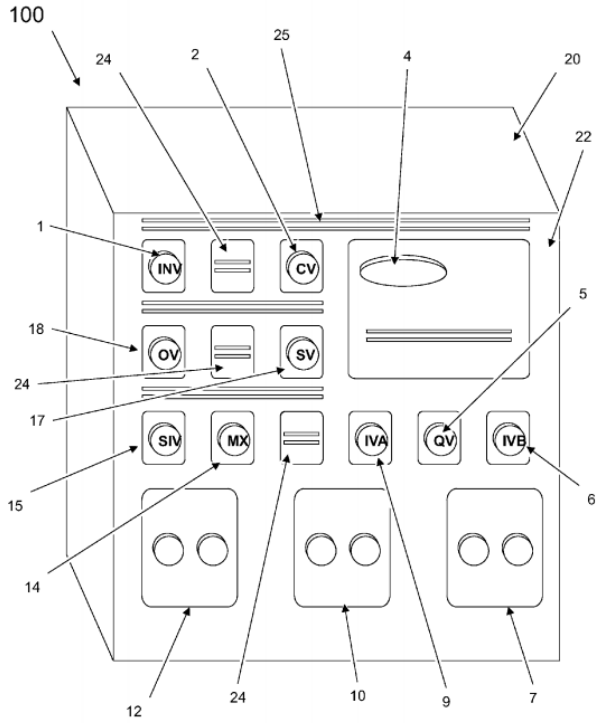

Fig. 2

Figure 2 is a schematic illustration of housing 20 with liquid handling panel 22 of the fluid handling system in the form of liquid chromatography system 100. Ex. 1001, 5:26–28. Liquid chromatography system 100 comprises a plurality of fluid control valves in the form of injection valve 1, column valve 2, quaternary valve 5, inlet valve B 6, inlet valve A 9, sample inlet valve 15, pH valve 17, and outlet valve 18. *Id.* at 5:31–35. Liquid chromatography system 100 further comprises UV monitor 4, system pump B 7, system pump A 10, sample pump 12, mixer 14, and three dummy modules 24. *Id.* at 5:35–38.

D. Illustrative Claim

Claim 1 is illustrative of the challenged claims and recites:

> 1. Automated fluid handling system comprising a housing and two or more interchangeable fluid handling units the housing comprising a liquid handling panel including two or more component positions for receiving said interchangeable

> units, wherein said units are arranged as interchangeable modular components, and include:
>
> a fluidics section;
>
> a non fluidics section comprising electronics or electrical components or control means; and
>
> a panel member arranged to separate the fluidics section from the non fluidics section and for attachment of the modular component to a component position of the liquid handling panel,
>
> and wherein the two or more component positions of the liquid handling panel are arranged for attachment of the panel members such that said respective fluidics sections are external to the housing and said respective non fluidics sections are internal to the housing.

Ex. 1001, 8:64–9:14.

Claims 2, 3, and 5 depend from claim 1 and, therefore, include the limitations of claim 1. Claim 2 further requires a sealing member that seals the interchangeable modular components against the liquid handling panel. *Id.* at 9:15–17. Claim 3 adds a master control unit to the fluid handling system, and requires that the interchangeable modular components are connected to the master control unit through a system bus providing electrical communication to each interchangeable modular component. *Id.* at 9:18–22. Claim 5 requires that the interchangeable modular components are of two or more sizes. *Id.* at 9:25–26.

II. DISCUSSION

Petitioner bears the burden of proving unpatentability of the challenged claims, and that burden never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). To prevail, Petitioner must establish the facts supporting its challenge by a preponderance of the evidence. 35 U.S.C. § 316(e);

37 C.F.R. § 42.1(d). Below, we discuss whether Petitioner has met its burden with respect to claims 1–3 and 5.

A. Level of Ordinary Skill in the Art

We begin our analysis by addressing the level of ordinary skill in the art. Petitioner argues, and Dr. Gale testifies, that a person of ordinary skill in the art relevant to the '718 patent "generally" would have had "a bachelor's degree in Mechanical Engineering, Bioengineering, or Electrical Engineering and three years of fluid handling machine design experience" or an advanced degree in any of those fields and at least one year of design experience. Pet. 19; Ex. 1018 ¶ 16. Mr. Söderman testifies that a person of ordinary skill in the art would have had "a scientific or technical background with at least 5 years of experience in the design, service of, operation, and/or use of automated fluid handling systems." Ex. 2009 ¶ 10.

The parties' proposals for the level of ordinary skill in the art have distinctions, e.g., "a bachelor's degree" versus "scientific or technical background," and "design experience" versus "design, service, operation, and/or use experience." We, however, find those distinctions to be of little consequence. An express definition of the level of ordinary skill is not required in all situations, as the prior art references can reflect the level of ordinary skill in the art. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (absence of specific findings on "level of skill in the art does not give rise to reversible error 'where the prior art itself reflects an appropriate level and a need for testimony is not shown'") (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985)). Neither party provides a sufficient explanation as to how either of the specific proposals regarding the level of ordinary skill changes the

analysis in this proceeding. We find the level of ordinary skill in the art to be reflected in the cited references.

To the extent that a more specific definition is required, we adopt the following as the level of ordinary skill in the art: the equivalent, through education or technical training and practical experience, of a bachelor's degree in mechanical engineering, bioengineering, or electrical engineering, and at least three years of experience in design, service, operation, and/or use of automated fluid handling systems. The definition we adopt is based on the testimony of the parties' experts, as well as our review of the '718 patent, the type of problems and solutions described therein, and the prior art involved in this proceeding.

B. Mr. Söderman's Qualifications as an Expert

Petitioner argues that Mr. Söderman's qualifications as an expert are "suspect" because Mr. Söderman: (1) does not have a university degree, (2) has not worked personally on the design of a chromatography system, and (3) does not have design experience in electrical engineering. Reply 16 n.4. Petitioner, however, does not move to exclude Mr. Söderman's testimony or take an express and affirmative position that Mr. Söderman is not qualified as an expert. *Id.* To the extent that Petitioner suggests as much, we disagree and find that Mr. Söderman is sufficiently "qualified in the pertinent art" to opine from the perspective of a person of ordinary skill in the art. *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1363–64 (Fed. Cir. 2008); *SEB S.A. v. Montgomery Ward & Co., Inc.*, 594 F.3d 1360, 1372–73 (Fed. Cir. 2010) (Federal Rule of Evidence 702 does not require a complete overlap between an expert witness's technical qualifications and the field of invention).

Specifically, Mr. Söderman has experience as a staff mechanical design engineer—a position in which he serves as a technical expert for Patent Owner's research and development unit. Ex. 2010, 1. Mr. Söderman also worked as a team leader overseeing a staff of mechanical design engineers and electrical design engineers during the development of Patent Owner's ÄKTA avant and ÄKTA pure chromatography systems, which Patent Owner identifies as commercial embodiments of the '718 patent. Ex. 2009 ¶ 3; Ex. 2010, 1–2; *see* Resp. 1–2, 52–53. Further, although Mr. Söderman did not receive a university degree, his testimony establishes that he received four years of formal instruction in mechanical engineering at a technical college. Ex. 1024, 3–4 (8:13–17, 9:11–10:12). Thus, Mr. Söderman's knowledge, skill, training, and experience in the field of automated fluid handling systems is sufficient to render him qualified to offer expert testimony in this proceeding. To the extent that Mr. Söderman is more familiar with the service, operation, and use of automated fluid handling systems and less familiar with their design or the design of their electrical components, we weigh Mr. Söderman's testimony accordingly, taking into account the extent of his expertise in those areas. *See, e.g.*, *Yorkey v. Diab*, 601 F.3d 1279, 1284 (Fed. Cir. 2010) (holding the Board has discretion to give more weight to one item of evidence over another "unless no reasonable trier of fact could have done so").

C. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under

that standard, claim terms are generally given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

In the Institution Decision, we provided a preliminary construction of several claim phrases, as reproduced in the table below:

Claim phrase	Construction
two or more interchangeable fluid handling units . . . wherein said units are arranged as interchangeable modular components (claim 1)	two or more fluid handling units of a standardized size and shape . . . arranged such that they may be used in place of other fluid handling units of the same standardized size and shape
fluidics sections are external to the housing and . . . non fluidics sections are internal to the housing (claim 1)	a fluidics section is on the outside of the housing and its respective non-fluidics section is on the inside of the housing

The parties do not dispute our preliminary construction of the phrase "fluidics sections are external to the housing and . . . non fluidics sections are internal to the housing." We have reconsidered that construction in light of the arguments and evidence adduced during trial, and maintain that construction based on the full record.

Patent Owner disputes our construction of the phrase "two or more interchangeable fluid handling units . . . wherein said units are arranged as interchangeable modular components," more particularly, our construction of the phrase "arranged as interchangeable modular components." Resp. 22–34. We address that dispute below.

The parties also address the construction of the phrase "connected to the master control unit by a system bus providing electrical communication

to each interchangeable modular component" recited in claim 3, as well as the term "each" within that phrase. Pet. 22–24; Resp. 34–39; Reply 10–13. For any limitation of claim 3 that requires express construction, we discuss that construction as part of our analysis of the ground of unpatentability.

1. *Two or more interchangeable fluid handling units . . . wherein said units are arranged as interchangeable modular components*

In the Institution Decision, we declined to adopt either Petitioner's or Patent Owner's proposed construction of the phrase "two or more interchangeable fluid handling units . . . wherein said units are arranged as interchangeable fluid modular components." Inst. Dec. 10. In particular, we explained that Petitioner's proposed construction failed to give effect to the term "interchangeable" as used in the disputed phrase. *Id.* We further explained that Patent Owner's proposed construction of the term "interchangeable" improperly read into the claim an embodiment described in the specification. *Id.* at 10–11. Based on our review and analysis of the claim language and written description, we determined that the claim language and written description embraced the ordinary and customary meaning of the term "interchangeable." *Id.* at 11.

Patent Owner disputes that conclusion, arguing that the broadest reasonable construction of the phrase "arranged as interchangeable modular components" should be interpreted to "include a requirement of ready interchangeability of the fluid handling units." Resp. 22. Patent Owner further argues that the interchangeability "necessarily relates to an end user of the automated fluid handling system, and not to a manufacturer constructing the system," and that claim 1 "necessarily includes, as part of the interchangeable fluid handling units, units that change the fluid flow of the system." *Id.*

Petitioner replies that the Board "correctly declined to include a requirement that the claimed 'interchangeable fluid handling units' be 'readily interchangeable.'" Reply 2. Petitioner further contends Patent Owner's arguments that the claims require interchangeability to relate to an end user of the system, and that the interchangeable fluid handling units must include units that change the fluid flow of the system, are arguments "for importing two *additional* requirements into the claims." *Id.* at 3.

A claim term will be interpreted more narrowly than its ordinary and customary meaning where the "patentee sets out a definition and acts as [its] own lexicographer," or the "patentee disavows the full scope of a claim term either in the specification or during prosecution." *Aventis Pharma S.A. v. Hospira, Inc.*, 675 F.3d 1324, 1330 (Fed. Cir. 2012). "The standards for finding lexicography and disavowal are exacting." *GE Lighting Sols., LLC v. AgiLight, Inc.*, 750 F.3d 1304, 1309 (Fed. Cir. 2014). To act as a lexicographer, "a patentee must 'clearly set forth a definition of the disputed claim term' and 'clearly express an intent to redefine the term.'" *Id.* (citation omitted); *see In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994) (any special definitions for claim terms or phrases must be set forth "with reasonable clarity, deliberateness, and precision").

Similarly, to disavow claim scope, "the specification or prosecution history [must] make clear that the invention does not include a particular feature." *GE Lighting*, 750 F.3d at 1309 (internal citation, quotation, and alterations omitted). To do so, the patentee may "include[] in the specification expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." *Aventis*, 675 F.3d at 1330 (internal quotations omitted). Ambiguous language does not constitute disavowal.

Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1323–26 (Fed. Cir. 2003). Nor is it sufficient "that the only embodiments, or all of the embodiments, contain a particular limitation." *Aventis*, 675 F.3d at 1330.

Beginning with the claim language, as we must, we note that claim 1 recites the term "interchangeable" in the phrase "arranged as interchangeable modular components" without further limitation or elaboration. In other words, the plain language of the claim does not include any requirement regarding how interchangeable the fluid handling units must be, to whom the fluid handling units must be interchangeable, or how the interchangeable units may or may not affect the fluid flow of the system. *See* Ex. 1001, 8:64–9:14.

Turning to the specification of the '718 patent, we find no special definition for the term "interchangeable." As we stated in the Institution Decision, "[t]he use of 'interchangeable' and related terms in the specification . . . does not indicate any deviation from its ordinary and customary meaning." Inst. Dec. 10. For example, the specification provides that the automated fluid handling system includes "a plurality of interchangeable modular components arranged in a liquid handling panel." Ex. 1001, 2:43–44; *see also id.* 5:45–5:50 ("The component positions are given a standard size and shape to provide simple interchangeability."); 6:37–41 (the system "may be configured for essentially any type of automated liquid handling operations provided that suitable fluid handling units are provided as interchangeable modular components for the system."). The specification also refers to the components provided in Figures 4a through 4d (e.g., valves, pumps, dummy components, and monitors) as types of interchangeable modular components. *Id.* at 5:58–6:14; *see also id.* at

2:46–64 (identifying the interchangeable modular components of Figure 1); 10:48–48 (claim 17, reciting that the interchangeable modular components include at least one of a number of valves, monitors, a system pump, and a dummy module).

Patent Owner contends that a construction of "interchangeable" that does not include ready interchangeability, such as the construction provided in the Institution Decision, improperly includes "a configuration expressly disclaimed in the specification of the '718 patent." Resp. 26. Namely, Patent Owner contends that the specification distinguishes fluid handling systems having fluid handling units that are "readily interchangeable" (i.e., the fluid handling systems recited in claim 1) from prior art systems "which are not." *Id.* at 28. As support, Patent Owner points to portions of the specification that describe prior art systems in which replacing defective fluid handling units was "a time consuming and delicate task," or systems that lacked "flexibility in adapting the instrument to a variety of different applications." *Id.* at 26–27 (citing Ex. 1001, 1:19–35, 36–41, 45–52).

Those portions of the specification, however, do not indicate a distinction between ready interchangeability and interchangeability. Rather, the specification distinguishes between systems that contain interchangeable components and those that do not (e.g., systems that require add-on equipment). *See* Ex. 1001, 1:19–35, 1:39–41 (explaining that most of the prior art liquid handling systems "lack . . . flexibility in adapting the instrument to a variety of different applications"), 1:49–51 ("One advantage with such [i.e., the recited] fluid handling systems is that the system may easily be upgraded without need for add-on equipment, and that the flow path may be easily optimized for new experimental setups."). Nor do we

find that the specification contains a clear teaching that Patent Owner intended a meaning of the term "interchangeable" that is narrower than its plain and ordinary meaning. *Aventis*, 675 F.3d at 1330; *see In re Man Mach. Interface Techs. LLC*, 822 F.3d 1282, 1287 (Fed. Cir. 2016). Thus, we do not find that the specification supports restricting the scope of the term "interchangeable" to units that are "readily interchangeable."[3]

Likewise, we do not find that the specification supports restricting the scope of the term "interchangeable" or the phrase "arranged as interchangeable modular components" to units that are interchangeable by the end user of the automated fluid handling system, or to units that change the fluid flow of the system. With regard to the former, although Patent Owner provides citations to the specification that it contends support such a restriction, *see* Resp. 30–31, we agree with Petitioner that the specification does not set forth "who must be the one to interchange the fluid handling units," or "use the word 'user.'"[4] Reply 8.

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[3] We focus our discussion on the specification because the prosecution history of the '718 patent was not submitted as evidence and, therefore, is not of record in this proceeding.

[4] Even if we agreed with Patent Owner that claim 1 requires interchangeability by an end user of the system, this proceeding does not turn on that issue of claim construction. Here, a preponderance of the evidence establishes that the descriptions and instructions provided in the 2040 Manual are intended for an end user of the system. Tr. 13:22–14:2; Ex. 1002, 9 (stating that the 2040 Manual "consists of different parts with different objects which are addressed to different user personnel"); Ex. 1024, 26 (98:2–6) (Mr. Söderman's testimony confirming that the 2040 Manual is "written for the end user"); *see id.* (98:7–99:1, 101:8–19).

With regard to the latter, the specification does refer to several embodiments in which the system is configured to adapt or extend the fluid flow path. Ex. 1001, 4:53–59. In those embodiments, additional optional valves can be added to the system, or standard fluid control valves can be moved to other positions.[5] *Id.* Yet, as explained above, the specification identifies pumps and monitors (in addition to valves) as types of interchangeable modular components of the system. *Id.* at 5:58–6:14; *see also id.* at 10:41–48 (claim 17, reciting that the "interchangeable modular components include at least one of," among others, "a system pump" and "a pump pressure monitor."). Thus, the specification is not limited to a particular embodiment or type of interchangeable modular component. Even if it was, however, it is improper to read an embodiment appearing in the written description into the claim if the claim language is broader than the embodiment. *In re Van Guens*, 988 F.2d 1181, 1184 (Fed. Cir. 1993); *see, e.g.*, *Golight, Inc. v. Wal-Mart Stores, Inc.*, 355 F.3d 1327, 1330–32 (Fed. Cir. 2004) (refusing to import a requirement into the claim, reasoning that a "particular advantage" described in the written description "is but one feature" among other disclosed features of the invention and each claim is not "limited to" such disclosed "advantage[] or feature[]"). Here, as

[5] Patent Owner appears to assert that the phrase "interchangeable modular components" refers only to the valves and excludes pumps and monitors described in the '718 patent specification. *See* Resp. 12. Mr. Söderman opines similarly. Ex. 2009 ¶ 71 ("Indeed, the '718 patent discloses that two or more pumps may be interchanged as fluid handling units and this interchanging would not alter or optimize the fluid flow path. However, these are additional elements that are optional in terms of their ability to be interchanged."). Neither Patent Owner nor Mr. Söderman, however, directs us to support for such a narrow reading of the phrase.

explained above, the claim language is broad and places no restriction on the term "interchangeable" or the phrase "arranged as interchangeable modular components."

Accordingly, for these reasons, and those provided in the Institution Decision (Inst. Dec. 9–11), we reaffirm our determination that, under the broadest reasonable construction, the phrase "two or more interchangeable fluid handling units . . . arranged as interchangeable modular components" means "two or more fluid handling units of a standardized size and shape . . . arranged such that they may be used in place of other fluid handling units of the same standardized size and shape."

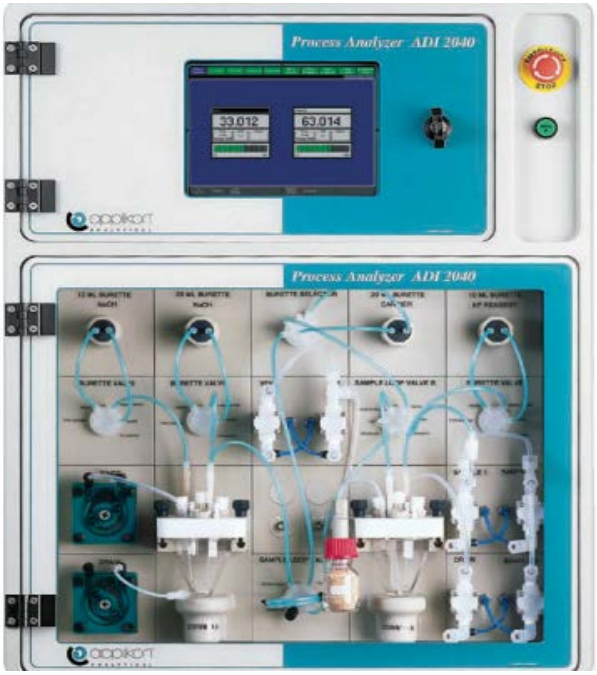
D. Anticipation of Claims 1–3 and 5 by the 2040 Manual

Petitioner contends that the 2040 Manual anticipates each of the challenged claims. Pet. 27–38. Patent Owner responds that the 2040 Manual does not disclose two or more interchangeable fluid handling units, as required by claim 1. Resp. 39–44. Patent Owner also argues that the 2040 Manual does not disclose that each fluid handling unit connects to and communicates with the master control unit over a system bus, as required by claim 3. *Id.* at 44–49. Based on our review of the arguments and evidence of record, we determine that Petitioner has demonstrated, by a preponderance of the evidence, that the 2040 Manual anticipates each challenged claim, as explained below.

1. The 2040 Manual

The 2040 Manual consists of seven parts that are "addressed to different user personnel" and describe, *inter alia*, the hardware, configuration, operation, and maintenance of an instrument that conducts

analyses using potentiometric and colorimetric methods. Ex. 1002, 9, 15.[6] The instrument has two lockable glass doors, the lower of which provides access to the wet part of the instrument. *Id.* at 15. The wet part includes "20 identical mounting positions for wet part modules, which can be placed in any of the available positions. This results in maximal flexibility for the wet part lay-out for numerous analysis configurations." *Id.* The construction of the wet part and wet part modules "ensures a strict separation between the wet part and the electrical part" of the instrument. *Id.* A figure from the 2040 Brochure[7] illustrating the instrument described in the 2040 Manual is reproduced below.

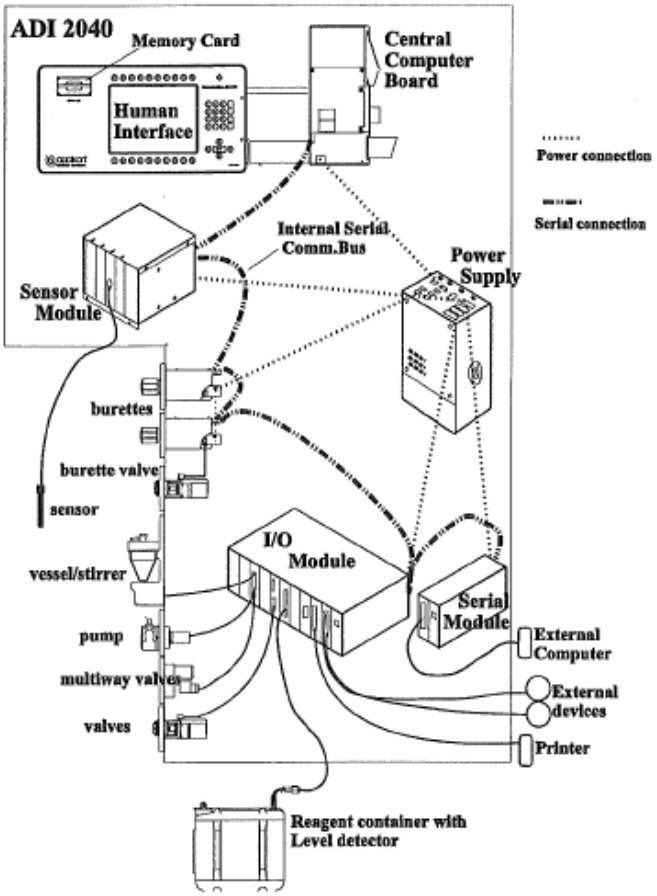


[6] Citations to all asserted prior art references are to the page numbers that Petitioner provides on the documents.

[7] Applikon Analytical B.V., ADI 2040 Process Analyzer Brochure (Ex. 1006). We provide a figure depicting a color version of the system described in the 2040 Manual, as shown in the 2040 Brochure, because the figure provided in the 2040 Manual is difficult to reproduce with visual clarity.

The figure illustrates the two lockable glass doors, as well as the twenty wet part mounting positions represented by four rows and five columns of squares. Ex. 1006, 2; *see* Ex. 1002, 15. As depicted, wet part modules are mounted in all of the available positions, but the 2040 Manual provides that wet part positions can be unused, in which case the those positions should be covered with a blind plate. Ex. 1002, 100. Wet part modules can be removed from the instrument and replaced by "unscrewing the module from the rear side of the door" and de-coupling the electric cable at the module. *Id.* at 577. If a wet part module is to be "removed permanently," it should be replaced by a blind plate. *Id.*

The instrument is controlled by a Computer Board Assembly and several modules, including an Input/Output ("I/O") module. The I/O module controls wet part modules, external devices, and communication with external devices, such as a remote control. *Id.* at 15. A schematic illustration is reproduced below.



The schematic illustration shows how the instrument is controlled by the central computer board, which uses an internal serial bus to interface the I/O module, serial module, sensor module, and burette modules. *Id.* at 16–17.

2. Analysis

Anticipation under 35 U.S.C. § 102 requires "the presence in a single prior art disclosure of all elements of a claimed invention arranged as in the claim." *Therasense, Inc. v. Becton, Dickinson & Co.*, 593 F.3d 1325, 1332 (Fed. Cir. 2010); *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008). We address first the disputed limitations of the challenged claims and then turn to the remaining limitations, which Patent Owner does not address in the Response.

a. Interchangeable fluid handling units . . . arranged as interchangeable modular components

All of the challenged claims require "two or more interchangeable fluid handling units . . . arranged as interchangeable modular components." According to Petitioner, the 2040 Manual discloses such interchangeable fluid handling units. Pet. 28–29, 31–33; Reply 14–15. In that regard, Petitioner identifies the twenty identical mounting positions, which can receive wet part modules. Pet. 28–29, 31–33. Petitioner also points to the 2040 Manual's statements that a wet part module can be (1) placed in any available mounting position, and (2) removed and replaced by unscrewing the module from the rear side of the door and disconnecting the cable that provides electrical connection. *Id.* at 29 (citing Ex. 1002, 15, 577). And Petitioner points to certain figures of the 2040 Manual that depict different arrangements or layouts of the fluid handling units in the system. Reply 15 (comparing Ex. 1002, 245, *with id.* at 252).

Patent Owner counters that several of the 2040 Manual's wet part modules, which are hardwired, are not "readily interchangeable," or "capable of [being] arranged by the end user of the equipment," and, therefore, are not interchangeable modular components. Resp. 39, 41–43. Patent Owner further contends that even if the burette modules can be easily relocated to a different position, they are not "interchangeable within the meaning of the '718 patent" because relocating them does not alter the fluid flow path of the system. *Id.* at 39–40, 43–44. Patent Owner's assertions are based on its proposed claim construction. Tr. 20:7–21:16 (confirming that Patent Owner's arguments regarding the limitations of claim 1 are based solely on applying Patent Owner's claim construction). We find Patent Owner's arguments unpersuasive because, as explained above, we do not

interpret "interchangeable fluid handling units . . . arranged as interchangeable modular components" to require ready interchangeability, interchangeability by an end user, and interchangeability that alters the fluid flow path of the system.

Under our claim construction, the claim limitation at issue requires only two or more fluid handling units of a standardized size and shape arranged such that they may be used in place of other fluid handling units of the same standardized size and shape. We find that the 2040 Manual teaches that limitation. The 2040 Manual explains that the wet part of the system "has 20 identical mounting positions for wet part modules, which can be placed in *any* of the available positions," resulting in "maximal flexibility for the wet part lay-out for numerous analysis configurations." Ex. 1002, 15 (emphasis added). The 2040 Manual provides mechanical schematics for each wet part module that show how each module is connected to the door and electrical part of the system. *Id.* at 101–71. Further, as Mr. Söderman's testimony confirms, the 2040 Manual describes how the modules can be removed and replaced. *Id.* at 577; *see also* Ex. 1024, 15 (55:6–56:2) (agreeing that the 2040 Manual describes removing a module by opening the wet part door, unscrewing the four screws that attach the module to the housing, and unplugging a cable); *id.* at 16 (60:11–20), 19 (72:13–73:5) (testifying that although the 2040 Manual does not provide step-by-step instructions for inserting a new module, like the '718 patent specification, the 2040 Manual describes inserting a new module by reconnecting an electrical cable); Ex. 1002, 149 (depicting three configurations of the stirrer/vessel module each with a different module (i.e., a first type of solenoid valve module, a second type of solenoid valve module, or a tubing

module) below it). Additionally, Dr. Gale testifies that the 2040 Manual describes a system "designed specifically so that one can mix and match and change the overall configurations and placements for the wet part modules depending on the application at hand." Ex. 1018 ¶ 48; *see id.* ¶¶ 86–87; Ex. 2011, 25:25–26:14, 26:20–27:6, 27:21–29:11, 41:21–42:24. We credit Dr. Gale's testimony in that regard, which is supported by the above-discussed teachings of the 2040 Manual.

Moreover, Patent Owner and Mr. Söderman agree that the 2040 Manual describes some interchangeability of wet part modules. Resp. 44 (explaining that the 2040 Manual describes two different layouts showing how the wet part modules "are put together into an actual system" and depicting those different layouts); Ex. 2009 ¶ 30 ("some minor re-configuration of the system [described in the 2040 Manual] is possible"). For example, Mr. Söderman testifies that the differently sized burette modules described in the 2040 Manual are modular components that can be exchanged with one another to inject or withdraw liquid samples at larger or smaller volumes. Ex. 2009 ¶ 70; Ex. 1024, 21 (80:19–81:12). Patent Owner agrees, noting that "one size Burette Module can be easily replaced with another size Burette Module." Resp. 7. The 2040 Manual also discloses that two or more or more burette modules can be used in the same system layout. Ex. 1002, 117, 119, 121, 123 (depicting the four different types of burette modules); *id.* at 252–53 (hydraulic planning sheets showing more than two burette modules in the layout of the system). Nevertheless, Patent Owner asserts and Mr. Söderman opines that exchanging the burette modules does not comport with the meaning of interchangeable because it "does not alter or optimize the fluid flow path of the liquid handling

system." Resp. 43–44; Ex. 2009 ¶ 70; Ex. 1024, 21 (81:12–16). As explained above, however, the claims do not require a change in fluid flow path. Given the foregoing, we find that Petitioner establishes, by a preponderance of the evidence, that the 2040 Manual discloses "two or more interchangeable fluid handling units . . . arranged as interchangeable modular components," as recited in claim 1 of the '718 patent.

b. The interchangeable modular components are connected to the master control unit by a system bus providing electrical communication to each interchangeable modular component

Claim 3 requires that the interchangeable modular components "are connected to the master control unit by a system bus providing electrical communication to each interchangeable modular component." Petitioner contends that the 2040 Manual discloses that limitation. Pet. 36–38. In particular, Petitioner asserts that the 2040 manual describes that the burette modules directly connect to and communicate with the central computer board over a system bus, and the other modules "first connect to the I/O modules which then use the system bus to communicate" with the central computer board (i.e., the connection and communication is indirect). *Id.* at 36–37 (citing Ex. 1002, 16–17). Dr. Gale testifies similarly, opining that the wet part modules are still connected to the central computer board and communicating over the system bus even though they have an intermediate component between them (the I/O card in the I/O module) that facilitates the transfer of information. Ex. 1018 ¶ 96.

Patent Owner agrees that all of the wet part modules except the burette modules are connected to the I/O module or sensor module in the layouts depicted in the 2040 Manual. Resp. 45 (citing Ex. 1002, 15, 289, 367, which all depict a first layout of wet part modules, and Ex. 1002, 252,

which depicts a second layout of wet part modules), 47 (citing Ex. 1002, 17); Tr. 25:22–3. Patent Owner asserts, however, that the wet part modules (other than the burette modules) do not connect to or communicate with the system bus in those layouts. Resp. 45. We disagree.

The 2040 Manual states that the process analyzer, which includes the wet part modules, "is controlled by" the central computer board in combination with the I/O module, a serial module, and a sensor module. Ex. 1002, 15. The I/O module controls the wet part modules, external devices, and communication with external devices. *Id.* The central computer board uses an internal serial bus for interfacing the I/O module, serial module, and sensor module, and burette modules (depicted above in § II.E.1). *Id.* at 16–17. The 2040 Manual also states that the system can include hydraulic planning sheets for the wet part. *Id.* at 252. One of the sheets, which Patent Owner reproduces in its Response, presents a hydraulic scheme or layout of the wet part. *Id.*; *see* Resp. 45. A second sheet indicates "the location of the wet part modules in the internal serial bus." Ex. 1002, 252. We find one of ordinary skill in the art would have understood, from the above-referenced disclosures of the 2040 Manual, that the wet part modules are connected to the master control unit, and that there is system bus communication to the wet part modules.[8] Though both the

[8] Referring to a schematic drawing of the pump module, Patent Owner also contends the cable depicted therein provides power to the pump component, "is not a 'system bus[,]' and does not include any communication" with the central computer board. Resp. 48 (citing Ex. 2009 ¶¶ 81–83, 85). Patent Owner's contention is based on Petitioner's alternative argument that the I/O card "could be considered part of the [m]aster [c]ontrol [u]nit." Pet. 37–38. In light of our findings above, we do not reach that alternative argument.

connection and communication are indirect (i.e., facilitated through the I/O card and I/O module, as Dr. Gale testifies), the parties agree that nothing in claim 3 requires a direct connection to, or direct communication through, the system bus. Pet. 23; Tr. 14:3–16, 16:16–19, 28:6–16. Accordingly, Petitioner establishes by a preponderance of the evidence that the 2040 Manual discloses the limitations of claim 3 of the '718 patent.

c. Additional limitations

Petitioner contends that the 2040 Manual discloses the remaining limitations of claim 1, and the additional limitations of claims 2 and 5. Pet. 27–29, 31–35 (discussing the remaining limitations of claim 1 and citing Ex. 1002, 15–17, 101–71, 252; Ex. 1018 ¶¶ 26–39), 36 (discussing claim 2 and citing Ex. 1002, 101–71), 38 (discussing claim 5 and citing Ex. 1002, 80, 145, 577). Patent Owner does not address the merits of Petitioner's assertions regarding those limitations. *See generally* Resp. In the Scheduling Order, we cautioned Patent Owner that any arguments for patentability not raised in the Response would be deemed waived. Paper 12, 2–3; *see also* 37 C.F.R. § 42.23(a) ("Any material fact not specifically denied may be considered admitted."). After having reviewed the unrebutted arguments and evidence presented by Petitioner concerning the remaining limitations of claim 1 and the additional limitations of claims 2 and 5, we are persuaded by those arguments, which we adopt as our own. *See* Pet. 27–29, 31–36, 38. Accordingly, we find that a preponderance of the evidence establishes that the 2040 Manual discloses those elements of claims 1, 2, and 5.

3. Conclusion

Based on our review of the record arguments and evidence, and for the foregoing reasons, we determine that Petitioner establishes, by a preponderance of the evidence, that the 2040 Manual anticipates claims 1–3 and 5 of the '718 patent.

E. Obviousness of Claim 3 Based on the 2040 Manual

Petitioner asserts that "[t]o the extent that the 2040 Manual does not disclose the modules being connected to the master control unit by a system bus," the subject matter of claim 3 would have been obvious to a skilled artisan "based on what is disclosed in the 2040 Manual." Pet. 43. As discussed in the previous section, we agree with Petitioner that the 2040 Manual discloses the limitations of claim 3. Accordingly, we need not reach Petitioner's alternative argument.

Had we determined that the 2040 Manual does not disclose the limitations of claim 3, however, we are not persuaded Petitioner shows sufficiently that the subject matter of claim 3 would have been obvious over the 2040 Manual.[9] Petitioner's argument that "having the I/O card on the modules is a design choice" is conclusory and does not provide articulated

[9] A patent claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). Obviousness is resolved based on underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness, i.e., secondary considerations. *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

reasoning with rational underpinnings as to why the ordinary artisan would have placed the I/O card on any wet part module other than a burette module. *KSR*, 550 U.S. at 418; *see In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016) ("To satisfy its burden of proving obviousness, a petitioner cannot employ mere conclusory statements."). Further, as Patent Owner points out, Dr. Gale identifies several advantages of placing the I/O card in a separate I/O module, as opposed to on the wet part module itself. Specifically, Dr. Gale opines that "it is more efficient and economical to make the I/O card separate for many of the modules" because "it makes the system more flexible and actually improves interchangeability." Ex. 1018 ¶ 98; Ex. 2011, 54:24–55:3; *see id.* at 55:5–16 (testifying that such placement would have allowed one to "easily swap in a new wet part module" and "connect it up" without "the expense or engineering to come up with that [the I/O card] on each module").

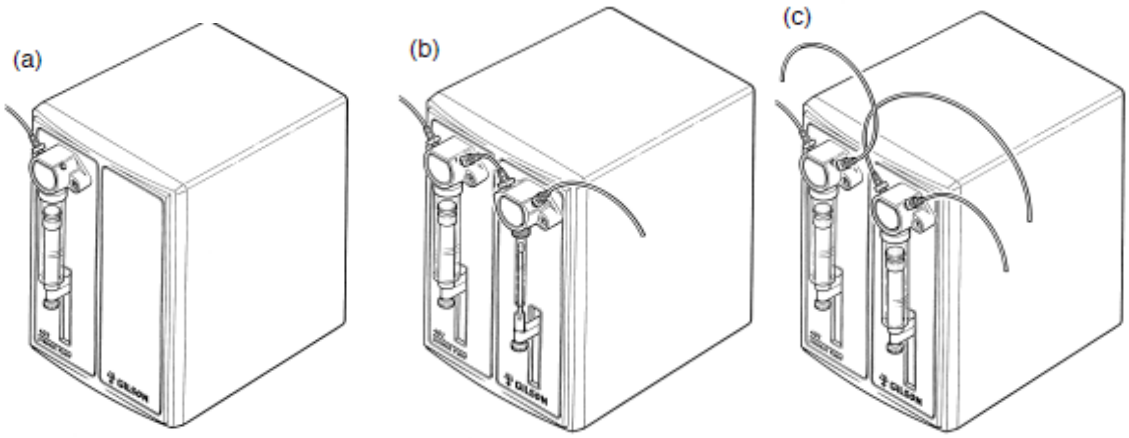
F. Anticipation of Claim 1 by the Gilson 402 User Guide

Petitioner contends that the Gilson 402 User Guide anticipates claim 1. Pet. 54–56. Patent Owner responds that the Gilson 402 User Guide does not disclose two or more interchangeable fluid handling units that are interchangeable modular components. Resp. 55–58. Based on our review of the arguments and evidence of record, we determine that Petitioner has not demonstrated by a preponderance of the evidence that the Gilson 402 User Guide anticipates claim 1, as explained below.

1. The Gilson 402 User Guide

The Gilson 402 User Guide describes a low pressure syringe pump for transferring liquids that includes three standard configurations: (1) single syringe, single valve; (2) dual syringe with Tee junction; and (3) dual

syringe, dual valve. Ex. 1011, 11. Figures of the three configurations are reproduced below.



Figures (a), (b), and (c) depict the three standard configurations of the syringe pump. *Id.* Figure (a) depicts the single syringe, single valve configuration, figure (b) depicts the dual syringe with Tee junction configuration, and figure (c) depicts the dual syringe, dual valve configuration. *Id.* The front panel of the instrument contains one syringe pump unit on the left, and one of three possible units on the right: a blanking plate, a syringe with Tee junction module, or another syringe and valve module. *Id.* at 16. The different configurations allow for "a wide range of applications" and the configuration used depends on the desired application. *Id.* The Gilson 402 User Guide describes how the system can be upgraded from a single syringe configuration (figure (a)) to a dual syringe configuration (figures (b) and (c)). *Id.* at 34–39.

2. Analysis

As explained above, claim 1 requires "two or more interchangeable fluid handling units . . . arranged as interchangeable modular components." Petitioner argues that the Gilson 402 User Guide discloses that limitation because it depicts the pump with a housing and two positions for inserting

syringe pump/valve modules that are the same size and shape. Pet. 54–55 (citing Ex. 2011, 11, 34). Petitioner and Dr. Gale further rely on the configurations provided in figures (a) and (b) (depicted above), and the instructions for upgrading the system from a single syringe configuration to a syringe and Tee junction configuration. *Id.*; *see* Ex. 2011, 60:21–24, 61:9–22. The instructions explain that a blanking plate is removed from the right side of the front panel and replaced by a Tee junction, which fits into the mounting recess. Ex. 1011, 35–36. The steps for making the upgrade include undoing the two nuts that secure the blanking plate inside of the front panel, removing the blanking plate, inserting the module into the mounting recess, and securing the module in place using the two provided screws. *Id.*

Patent Owner argues that the Gilson 402 User Guide does not include any teaching that the syringe on the left side of the instrument "is capable of being removed" and interchanged with another module. Resp. 57. Like Petitioner, Patent Owner points to the instructions in the Gilson 402 User Guide for upgrading the system. *Id.* at 56–57. Patent Owner asserts, however, that each of the upgrades requires exchanging components on the right side of the instrument, but not on the left side. *Id.* at 57; Ex. 2009 ¶¶ 87–89. In sum, Patent Owner argues that only one unit in the Gilson instrument (i.e., the unit on the right hand side) "is available for upgrading or interchanging," which does not meet claim 1's requirement of at least two units that "are 'arranged such that they may be used in place of other fluid handling units of the same size and shape.'" *Id.* at 56 (quoting Inst. Dec. 11). We agree with Patent Owner.

Petitioner admits that the Gilson 402 User Guide "depicts the left module as stationary." Reply 23–24. Further, as Patent Owner points out, the Gilson 402 User Guide explains that "the front panel of the instrument contains a syringe pump unit . . . on the left, and one of three possible units on the right: a blanking plate, a syringe and Tee junction module, or another syringe and valve module." Ex. 1011, 16; *see* Resp. 57. That teaching is consistent with the instructions for upgrading the system, which are directed to replacing or exchanging components on the right side of the system. *See* Ex. 1011, 34–39. For example, the instructions state that a user "can install a second module on the front panel so that your syringe pump has two syringes. The right hand module can be a Tee junction or a second valve." *Id.* at 33. The instructions go on to explain that the "syringe and Tee junction module must be mounted on the right of the 402 [instrument]" and depict replacing the module (a blanking plate) on the right hand side with the Tee junction module. *Id.* at 34. The Gilson 402 User Guide also describes upgrading to a dual syringe and valve configuration by removing the Tee junction module from the right side of the instrument and replacing it with a syringe and valve module. *Id.* at 39.

Petitioner argues that the Gilson 402 User Guide describes the syringe module on the left side "as 'function[ing] in the same way' as the second [syringe] module." Reply 23 (quoting Ex. 1011, 21). Petitioner, however, does not direct us to any description in the Gilson 402 User Guide disclosing or suggesting that the syringe on the left side (even if it functions identically to the syringe on the right side) can be exchanged with another component. *See generally* Pet.; Reply.

Petitioner also argues that the Gilson 402 User Guide "consistently depicts [the left module] as identical to the second syringe and valve module, to be mounted on the right side, suggesting that they can in fact be interchanged" *Id.* at 24. Yet, neither Petitioner nor Dr. Gale identifies anything in the Gilson 402 User Guide disclosing or suggesting that the syringe module on the left side can be removed, much less inserted into a different position. Rather, Dr. Gale agrees that, even though he relied on pages 34, 35, and 39 of the Gilson 402 User Guide to illustrate the interchangeability of the left side syringe pump module, those pages do not indicate whether that module can be removed from the device. Ex. 2011, 60:21–62:2.

In any event, Petitioner's assertion that the depiction of the two syringes as identical suggests that they are, in fact, interchangeable rests on attorney argument that is insufficiently supported by the record developed during trial. Petitioner, therefore, does not demonstrate by a preponderance of the evidence that the Gilson 402 User Guide discloses "two or more interchangeable fluid handling units . . . arranged as interchangeable modular components," as set forth in claim 1 of the '718 patent.

3. Conclusion

Based on our review of the record arguments and evidence, and for the foregoing reasons, we determine that Petitioner does not demonstrate, by a preponderance of the evidence, that the Gilson 402 User Guide anticipates claim 1 of the '718 patent.

G. Motion to Exclude

We turn next to Patent Owner's Motion to Exclude. *See* Papers 32, 26, 37. Patent Owner moves to exclude Exhibits 1022 and 1023, as well as

the corresponding portions of Petitioner's Reply that rely on Exhibit 1022. Paper 32, 1. Because our decision does not rely on either of the challenged exhibits or the portions of Petitioner's Reply that rely on Exhibit 1022, we dismiss Patent Owner's Motion to Exclude as moot.

III. CONCLUSION

For the foregoing reasons, we determine that Petitioner has established, by a preponderance of the evidence, that claims 1–3 and 5 of the '718 patent are unpatentable under 35 U.S.C. § 102(b) as anticipated by the 2040 User Manual.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–3 and 5 of the '718 patent are *unpatentable*;

FURTHER ORDERED that Patent Owner's Motion to Exclude (Paper 32) is *dismissed* as moot; and

FURTHER ORDERED that this is a Final Written Decision; therefore, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

IPR2015-01826
Patent 8,821,718 B2

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EXHIBIT E

F65ggehh

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
----------x

GE HEALTHCARE BIO-SCIENCES AB, GE HEALTHCARE BIO-SCIENCES CORPORATION, and GENERAL ELECTRIC COMPANY,

Plaintiffs,

v. 14 Civ. 7080 (LTS)

BIO-RAD LABORATORIES, INC.,

Defendant.

----------x

New York, N.Y.
June 5, 2015
9:30 a.m.

Before:

HON. LAURA TAYLOR SWAIN,

District Judge

APPEARANCES

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DAVID BILSKER
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ANNE TOKER
SKY ADAMS

here removed and you put it side-by-side with the Bio-Rad module, how would that compare to those two figures I just showed you?

A. It would look exactly the same.

Q. Can we go to that portion that says "hardware" on the same page. And right in the middle it says the "ADI 2040." Do you see that? Highlight that and go on to the next line and the next. Keep going.

What do you understand it to mean when it says the ADI 2040 has a modular wet part with 20 uniform positions?

A. It's a modular instrument that has these 20 different positions that you can see in the picture in the upper left here, and these modules can be moved around readily and easily; that's what the flexibility of modular design clearly implies.

Q. So you just were sitting here when Mr. Wolf was asking Dr. Kearl questions about modularity and flexibility and whether those drove sales. The words modularity and flexibility as they're used here with the 2040, how do you understand that in relation to the way that Mr. Wolf is using it?

A. Well, I understand that they -- they're very similar.

Q. When it says that -- the 2040 manual says that the 2040 can be used for -- configured for almost any application, what do you understand that to mean?

A. That means that it can be used for a wide variety of wet

chemistry or liquid chromatography applications.
Q. Would you understand the 2040 to be saying that it can only be used for those four or five applications that are actually described as having software packages?
A. Certainly not. There's literally thousands of applications that this 2040 instrument can be used for.
Q. You've looked at the two claims in the '718 patent that relate to chromatography, correct?
A. I have.
Q. What extra structural elements do those claims identify over, say, claim 1, which is an automated liquid -- automated fluid handling system?
A. None.
Q. In your box there, you have something marked as DDX, I believe it's 6 or 7, which is a column. Can you pull that out.
You relied in part on a declaration from Mr. Koshy who said that the 2040 could be used with a module to perform chromatography. Do you recall that?
A. I do.
Q. How, if at all, do you relate what you have in your hand, that column, to, say, the module that Mr. Koshy was identifying?
A. This would be the module that would be required to complete that, to perform the chromatography.
Q. What is the 2040 machine designed for as far as delivering

controlled fluid flow?
A. That's primarily what it's for, to deliver a controlled fluid flow and to basically turn on and off different flows.
Q. Can we put that picture of the 2040 back up.
When you say deliver controlled fluid flow, can you describe what you mean by that.
A. They would be able to deliver flows at basically either a continuous rate or at a controlled rate, one that you could define.
Q. So you see in that picture that we have up, we have that one component kind of in the middle with a red collar on it?
A. Yes.
Q. And there seem to be tubes going in and out of that one, is that right?
A. Yes.
Q. What would you do to, say, put the column that you have in your hand, the DDX6, in place of that?
MS. SKLENAR: Objection. None of this is in his declaration.
MR. BILSKER: It would be impossible to put it in his declaration to reply to Dr. Scandella when Dr. Scandella's declaration submitted a supplemental declaration that we never had an opportunity to reply to unless he was clairvoyant and knew exactly what Dr. Scandella was going to say. There has been no opportunity to identify that. He's merely replying to

what Dr. Scandella said.

MS. SKLENAR: May I reply to that.

THE COURT: Briefly.

MS. SKLENAR: Dr. Gale has a section in his report explaining why he thinks this is a liquid chromatography system. He doesn't mention any of these arguments.

THE COURT: Overruled. I'll allow it.

Q. What would you do to put the chromatography column there in place of, say, that end of the red collar?

A. You'd just disconnect the tubes from the red item and then you would attach them at the top and the bottom of this particular instrument.

Q. How long do you think that would take you?

A. Two minutes.

Q. Dr. Gale, let's turn to exhibit 109 -- excuse me -- exhibit 108, which is the 2040 brochure. I'm sorry. Exhibit 109 is the 2045 brochure.

THE COURT: What was the number again of the column?

Q. Can you read off that number.

A. DDX6.

THE COURT: You offer that?

MR. BILSKER: I offer that into evidence, your Honor.

MS. SKLENAR: No objection.

THE COURT: DDX6 is admitted.

(Defendant's Exhibit DDX6 received in evidence)

EXHIBIT F

INTENTIONALLY OMITTED

EXHIBIT G

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

Cytiva Sweden AB and Global Life Sciences Solutions USA, LLC,
Plaintiff, Case No. 18-1899-CFC
-against-
Bio-Rad Laboratories, Inc.,
Defendant.

HIGHLY CONFIDENTIAL
VIDEO-RECORDED DEPOSITION OF
DR. BRUCE GALE
Zoom Videoconference
11/25/2020
8:28 a.m. (MT)

REPORTED BY: AMANDA GORRONO, CLR
CLR NO. 052005-01

DIGITAL EVIDENCE GROUP
1730 M Street, NW, Suite 812
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11/25/2020

8:28 a.m. (MT)

VIDEO-RECORDED DEPOSITION OF DR. BRUCE GALE, held virtually via Zoom Videoconferencing, before Amanda Gorrono, Certified Live Note Reporter, and Notary Public of the State of New York.

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(Via Zoom Videoconferencing

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Andy Mortensen, legal videographer, Digital Evidence

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EXHIBITS

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A. Yes.
Q. But you can't tell me which portions you wrote?
MR. DAMON: Objection; form.
A. This was four years ago. I mean, he wrote up a -- he and I talked about an outline. He wrote up some pieces, I wrote up some pieces, we put them together. He -- I don't know. We worked together on writing the report.
Q. Okay. We're going to come back to this. Did you personally record any videos relating to the work that was done on the 2040 System?
A. Not at that time. I mean, I've taken some videos of -- well, I don't think so. I was trying to think if I took any other videos of that, but I don't -- I don't think so.
Q. So you personally haven't recorded any videos relating to any work on the 2040 System; is that right?
A. When we -- I know we took some pictures. And, you know, more recently when we were checking on some things about processors and some

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other things like that in the 2040 System, we may have taken some videos. I don't specifically recall.
Q. So you don't know one way or another whether you recorded any videos related to work on the 2040 System?
MR. DAMON: Objection to form.
A. Yeah, I don't specifically recall if a video was taken or not. I mean, the videos that I've presented to you were not ones that I took myself. But I've -- I've taken pictures myself personally, and there may have been video or two in there. I don't recall.
Q. The videos that were presented with your report, you don't appear on those videos, right?
A. That's correct.
Q. And who recorded these videos?
A. Kevin Petersen.
Q. You weren't present when those videos were recorded, correct?
A. I was in the building I was in my office across the hall watching while they did it. So I don't know what "present" means.

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Q. Could you see the experiments going on, as they were occurring?
A. Yes, my office window looks directly into my lab.
Q. Okay. So your testimony was you actually were sitting there watching the experiments?
MR. DAMON: Objection to form.
A. My testimony was that I was present, and that I could check on them whenever I wanted to.
Q. And you're -- you're basing that off of your recollection from what happened in 2016, right?
MR. DAMON: Objection to form.
A. Yes. And -- and I'm not saying -- I mean, those videos are hours long, right? So I may or may not have been there the entire time. But I do recall being in the building when Kevin and -- when Kevin did the experiments.
Q. How many times did you -- did you check on the experiment?
MR. DAMON: Objection; form.
A. You know, I don't -- I don't recall.

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I know that I went in, saw it set up. You know, they -- I mean, I -- he -- Kevin was excited to show me that it was working and things like that. So I went in at least a couple of times.
Q. And do you recall what you specifically said?
A. I don't recall saying -- I don't recall now.
Q. Right. So -- so we're talking about four years ago, right?
A. Yep.
Q. Okay. So is there anything else you specifically recall, that you can testify under oath, occurred in November of 2016, in terms of your -- your going in to check or discussions that were had about the experiments?
A. I mean, you're asking almost an impossible question, that if it had happened last week I don't know if I could have -- I could answer in a reasonable way.
The question, as I interpret it, is, was I present? Was I involved with this process?

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Yes. Did I see what happened? Yes. Do I have videos that show that the whole thing worked? Yes. Did I understand how they programmed it? Did I understand what they moved around? Did I understand how the wiring and other things were done? Yes, I understand all of these things. I was present, I looked at it, I was involved.

Q. Okay. But do you recall anything else about specific discussions that occurred during those experiments in November 2016?

A. I mean, I meet with -- met with Kevin on at least a weekly basis, and often more often -- or more than that in this time frame. And we'd talk about, you know, the experiments, what they were trying to do, how they were going about it. I don't remember the details, but I remember that they took place, so...

Q. So you can't tell me any more about specific discussions that occurred in November 2016, correct?

A. No. I mean, well, you have everything that I have.

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Q. Okay. And you can't tell me more about the specific portions of the experiment that you personally observed, correct?

MR. DAMON: Objection; form.

A. Yeah. I don't recall specifically whether I watched this part or that part. But I do recall seeing the separations when they were done. I recall seeing the, you know, the machine in operation. That -- that's what I recall.

Q. You mentioned earlier that they moved parts around. Do you remember saying that?

A. Yeah. Some of the modules.

Q. Okay. So what do you recall specifically about what Mr. Petersen and Mr. White did in terms of moving modules around?

A. I asked them to move some modules. They -- I think -- I believe they videotaped that. They, you know, unscrewed the modules, moved them, you know, took one out -- or took two of them out, moved the one up. I think they actually moved four of them. And I -- actually, I did that on occasion with them so I understood how it happened and what it

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took and how hard or easy it was. So I've done that as well.

Q. So when did you do that?

A. I did that in 2016. I actually did it about a month ago too.

Q. So when you did it in 2016, which modules did you move around?

A. You know, I don't specifically recall. I believe in the report it says specifically which ones Kevin and Travis moved as part of the demonstration.

Q. But you don't recall which ones you moved around; is that right?

A. Yeah, I don't. You know, I probably started in the top left corner or something like that.

Q. You don't know for sure, do you?

A. No.

Q. Okay. And did you -- did you record the time it took somewhere?

MR. DAMON: Objection.

A. Did I -- did I record when I did it?

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Q. Yes.

A. I don't think so.

Q. So you didn't do that in 2016? You didn't actually use a stopwatch and record how much time it took you to move modules around, right?

A. No. Kevin and Travis did that, so I didn't do it separately.

Q. And when you said you experimented with moving modules around over the last month, is that right?

A. Yes.

Q. And when was that exactly?

MR. DAMON: Objection.

A. I don't know. Five weeks ago, something like that, six weeks ago.

Q. Was that before you finalized your first report?

A. I don't specifically recall. I think it was before the second report, but I'm not going to stake my life on that one.

Q. Which modules did you move around?

A. Moved around specifically -- well

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that there's a manual that has been -- is part of the prior art appendix that you provided for the 2040 System?
A. That's correct.
Q. It's a lengthy manual, right?
A. It is, indeed.
Q. Have you read the entire thing?
A. I have not read the entire thing.
Q. Which parts have you read?
A. I've -- well, I've, you know, looked over it briefly. I've -- let's see, I'd have to pull it up to probably answer that question.
Q. So are you doing that?
A. I can.
Q. Well, do you -- what parts, if any, do you recall right now? Without reference to the manual.
A. I mean, I specifically went through all of the drawings of all the parts and the description of all the modules. I went through the description of how the -- how to program the system, how it works. I read the introduction. I've read, I

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think -- anyways, how to use it, change it, operate it. But as you note, it's quite long. There's some parts that aren't as relevant.
Q. How did you obtain the 2040 System that was in your lab?
A. It was -- I don't remember the exact details at this point, but it was -- I think it was -- we found one that we could purchase and Bio-Rad purchased that, and had it shipped to my lab.
Q. How much was it purchased for?
A. You know, I don't recall right off.
Q. Any ballpark estimate?
A. I don't know. $10,000, something like that.
Q. How much were the systems when they were sold in the -- like, let's say 2008, 2009 time frame by Applikon?
A. You know, I don't know.
Q. Do you have any understanding, in terms of ballpark?
MR. DAMON: Objection to form.
A. I have not looked to figure that out.

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Q. So it could be $25,000, $50,000, $100,000, more. You don't know, correct?
MR. DAMON: Objection; form.
A. You're correct. I don't -- I don't know what the typical sales price was.
Q. Okay. Do you know the price that any system sold for prior to the 2010 time period?
A. I vaguely remember that Mr. Koshy might have said something to that effect, but I don't remember.
Q. Do you know what the profit margin was? Or do you know what the profit margin was for Applikon, the manufacturer of those systems?
A. I don't recall.
Q. Did you ever know what the profit margin was?
A. I don't know if I knew. I don't recall that coming up, but I may have known it at some point.
Q. Did you ever know the price the system sold for?
MR. DAMON: Objection to form.

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A. Again, I read, you know, a number of Metrohm documents that might have come up in the deposition of some of the Metrohm folks. I don't remember.
Q. You're not sure one way or another what the price was, correct?
A. Correct.
Q. Has the 2040 System that -- that Bio-Rad shipped to you -- first of all, when did you receive that?
MR. DAMON: Objection; form.
A. I believe it arrived in 2016. I don't remember the precise dates or anything like that.
Q. You can't remember exactly when you received the 2040 System that Bio-Rad arranged for?
A. I mean, it was sometime in 2015 or 2016.
Q. Okay. Has that system been basically within your custody since then? Since you acquired it?
A. Yes.

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Q. And where has it been this whole time?
A. It's been in my lab the entire time, other than when it's been in my office recently.
Q. And why was it moved to your office?
A. So that your attorneys could come and look at it.
Q. Okay. And what is your lab?
MR. DAMON: Objection; form.
A. I mean, what do you mean by what is my lab?
Q. I mean, how many -- how many liquid chromatography systems are in your lab?
A. Depends on how you count liquid chromatography systems, but I have probably three or four.
Q. What -- what liquid chromatography systems -- and we're going to come back to the -- the 2040 System, but setting that aside, what other systems that you considered to be liquid chromatography systems have you had in your lab?
A. So all the liquid chromatography

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systems I have, we built ourselves.
Q. Okay. And are those systems that you or your students use?
A. Yeah. We use them every day.
Q. So if I understand your testimony, you have three or four systems that are liquid chromatography systems in your lab, that you or your students have built, that are used every day?
A. We don't use all three or four of them every day, but we use one or the other of them pretty much every day. Probably not every Sunday or something like that, but I do research with these instruments, I use them regularly. They are a major part of what I do in my lab.
MS. SKLENAR: Now, why don't we go to Tab G and mark that as the next in order.
THE TECH: (Complying.)
(Whereupon, Exhibit 335, List of Programs on the 2040 Instrument, was marked for identification.)
Q. If we can blow up so we can read what's on the monitor, please?

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A. Sorry. Did you say Tab G?
Q. Yes.
A. Because I don't see that in my list.
Q. It should appear.
THE TECH: Yeah, it takes just a little -- there's a little bit of lag time between when it comes up. It's Exhibit 335. It should be there now if you refresh your web browser.
THE WITNESS: Okay.
MS. SKLENAR: It should also be on the screen.
Q. Do you recognize this Exhibit 335?
A. Yes.
Q. And this is a list of what?
A. These are -- it looks like the list of different programs on the 2040 instrument that's in my office presently.
Q. And did it -- when the system was delivered to you, did it have all of these programs on it?
A. It had several programs on it. I don't remember exactly what all of them were, but in

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fact, most of these were already on it.
Q. Which of these programs listed on Exhibit 335 were added by individuals in your lab?
A. I can't be positive exactly, but like the chrom test, the chrom test2, the chrom test2 copy, probably that chrom2 and maybe the chrm_gradient one. The other ones I -- I'm not positive about.
Q. Okay. Who programmed -- so let's focus on the one that starts with chrom. Who programmed chrm_gradient?
A. I mean, it would have been one of my students, either Kevin or Travis, if -- the -- I know the chrom2, the chrom test2, the chrom2 and the chrom test were ones that we did. The chrm_gradient may or may not have been ours. But that would have been done by either Kevin or Travis if it was done by us.
Q. You're not sure if anyone in your lab did chrm_gradient?
A. I'm not positive.
Q. And if someone in your lab did the chrm_gradient, you're not familiar with the efforts

CERTIFICATE OF SHORTHAND REPORTER-NOTARY PUBLIC

I, Amanda Gorrono, the officer before whom the foregoing depositions were taken, do hereby certify that the foregoing transcript is a true and correct record of the testimony given; that said testimony was taken by me stenographically and thereafter reduced to typewriting under my direction; and that I am neither counsel for, related to, nor employed by any of the parties to this case and have no interest, financial or otherwise, in its outcome.

IN WITNESS WHEREOF, I have hereunto set my hand this 25th day of November, 2020.

_____

AMANDA GORRONO, CLR
CLR NO: 052005 - 01

Notary Public in and for the State of New York
County of Suffolk
My Commission No. 01G06041701
Expires: 01/07/2023

Bruce Gale, Ph.D., c/o
Quinn Emanuel Urquhart & Sullivan, LLP
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Case: Cytiva Sweden AB, et al. v. Bio-Rad Laboratories, Inc.
Date of deposition: November 25, 2020
Deponent: Bruce Gale, Ph.D.

Please be advised that the transcript in the above referenced matter is now complete and ready for signature. The deponent may come to this office to sign the transcript, a copy may be purchased for the witness to review and sign, or the deponent and/or counsel may waive the option of signing. Please advise us of the option selected. Please forward the errata sheet and the original signed signature page to counsel noticing the deposition, noting the applicable time period allowed for such by the governing Rules of Procedure. If you have any questions, please do not hesitate to call our office at (202)-232-0646.

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SIGNATURE PAGE
Case: Cytiva Sweden AB, et al. v. Bio-Rad Laboratories, Inc.
Witness Name: Bruce Gale, Ph.D.
Deposition Date: November 25, 2020

I do hereby acknowledge that I have read and examined the foregoing pages of the transcript of my deposition and that:

(Check appropriate box):
( ) The same is a true, correct and complete transcription of the answers given by me to the questions therein recorded.
( ) Except for the changes noted in the attached Errata Sheet, the same is a true, correct and complete transcription of the answers given by me to the questions therein recorded.

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ERRATA SHEET

Case: Cytiva Sweden AB, et al. v. Bio-Rad Laboratories, Inc.
Witness Name: Bruce Gale, Ph.D.
Deposition Date: November 25, 2020
Page No. Line No. Change

_____ _____
Signature Date

EXHIBIT H

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

CYTIVA SWEDEN AB, and GLOBAL LIFE SCIENCES SOLUTIONS USA LLC, Plaintiffs v. BIO-RAD LABORATORIES, INC., Defendant.	C.A. No. 18-1899-CFC Consolidated **DEMAND FOR JURY TRIAL** **HIGHLY CONFIDENTIAL (TECHNICAL) – ATTORNEYS' EYES ONLY**

OPENING EXPERT REPORT OF DR. BRUCE GALE

4. I attach as Exh.[1] 1 my *curriculum vitae*, which includes a complete list of my qualifications.

5. I received a bachelor's of science degree in Mechanical Engineering from Brigham Young University in 1995 and received my Ph.D. in Bioengineering from the University of Utah in 2000. My thesis was on the development, fabrication, and testing of a microscale electrical field flow fractionation system, a type of liquid chromatography system. This project involved the development of this new chromatography technique as well as all the liquid handling, connections, and detection components. Furthermore, I was involved in research and design of all fluid handling components for both macroscale and microscale versions of multiple other types of field flow fractionation systems.

6. Since receiving my Ph.D. I have been continuously involved in academia. I am currently a Professor of Mechanical Engineering at the University of Utah and am the Director of the State of Utah Center of Excellence for Biomedical Microfluidics as well as the College of Engineering Nanofabrication Lab. I am also an Adjunct Professor at the University of Utah in the Departments of Bioengineering, Electrical and Computer Engineering, and Materials Science. I was named Researcher of the Year in 2012, 2013, and 2016 for the Mechanical Engineering Department at the University of Utah. I recently received the Distinguished Research Award from the University of Utah at the May 2020 graduation.

7. As part of my work as a scientist and researcher, I have published more than 350 articles, more than 140 of which are published in archival journals such as: *Analytical Chemistry*, *Analytical and Bioanalytical Chemistry*, *Journal of Chromatography*, *Analyst*, *Analytical Methods*, *Electrophoresis*, *Journal of the Electrochemical Society*, *Sensors and Actuators*, *Lab*

[1] Exh. __ refers to exhibits attached to this report unless otherwise noted.

on a Chip, *Langmuir*, and other top chemistry and engineering journals. I have written 5 book chapters as well. These papers and book chapters cover a wide range of topics, but primarily center on microfluidic devices for biology and chemistry. About 1/3 of my papers are for the design and characterization of field flow fractionation instruments, which is a type of liquid chromatography. These papers on field flow fractionation papers reflect our efforts to design and automate a variety of chromatography systems. Many of my other papers discuss issues related to the Asserted Patents including: liquid handling sensors, conductivity sensors, oxygen sensors, optical detection systems, liquid handling component automation and integration, control systems for liquid handling devices, and other analytical devices.

8. I have taught several courses related to the Asserted Patents. First, I have taught our senior design course on two occasions. This course requires seniors in Mechanical Engineering to design and develop their own products. As part of this course, it was my responsibility to teach important engineering design principles, review the progress of the design teams, and guide these teams in their progress. Many of these projects involve automation, fluidics, and electronics. I also regularly teach a class on microfluidics, which is the science and engineering of small scale fluidics. In this course I teach principles of fluidic automation, fluid component engineering, fluid physics, and system manufacturing. I have also taught courses on: dynamics, physiology, biosensors, biomaterials, and microelectromechanical systems (MEMS). Furthermore, I have advised graduate students in many related areas of study including: pumps, valves, chromatography systems, biosensors, optical detection techniques, highly-parallel surface plasmon resonance (SPR) systems, automated sample preparation systems, biomolecule analysis systems, and medical devices.

280. In all cases, I applied the agreed claim constructions or the Court's constructions in performing my analyses and rendering my opinions in this report.

VI. SUMMARY OF OPINIONS

281. It is my opinion that certain prior art references and systems anticipate and/or render obvious all the Asserted Claims of the Asserted Patents.

282. As set forth in detail below, it is my opinion that the Asserted Claims of the Asserted Patents—claims 1, 2, 4, 6-10, 12-17, 19-21, 23-27, and 30 of the '589 patent, claims 1-4, 10, 12-14, 17, and 18 of the '590 patent, claims 9, 14, 26, and 27 of the '591 patent, claims 1, 4-9, 15, 25, 27, 29, and 30 of the '420 patent, and claims 16, 19, 20, 22, 25, 27, 28, 30, and 33-35 of the '124 patent—are invalidated by each of the following prior art references:

- The 2040 System alone or in combination with the 850 System and/or the 811 System and/or the Agilent 1100/1200 Series and/or Hess and/or the DuoFlow System and/or Wendell
- The 850 System alone or in combination with the 811 System and/or the Agilent 1100/1200 Series and/or Hess and/or the 2040 System and/or the DuoFlow System
- The NGC Prototype System alone or in combination with the 2040 System and/or the 850 System and/or the DuoFlow System and/or the Agilent 1100/1200 Series

283. It is also my opinion that the Asserted Claims of the Asserted Patents are invalidated for lack of written desciption, lack of enablement, and/or indefiniteness under Section 112.

284. It is further my opinion that the Asserted Claims of the Asserted Patents are invalidated for improper inventorship.

285. In the following sections, I provide a narrative of my opinions.

VII. DESCRIPTION OF THE STATE OF THE ART AND SUMMARY OF PRIOR ART REFERENCES

(2040 Brochure at BRGE00001521-22; *see also* 2040 Manual at BRGE00003266-67.[120])

299. I have inspected and analyzed a 2040 System that I have in my laboratory. I also performed tests to show the 2040 System can deliver controlled fluid flow to and through a liquid chromatograph column and which I consider an automated liquid chromatography system capable of performing automated liquid chromatography. The tests are described in the test report, attached as Exh. 4. I recorded videos of these tests showing the 2040 System performing liquid chromatography. A video of the test conducted on November 12, 2016 is attached as Exh. 5 and a video of the test conducted on November 14, 2016 is attached as Exh. 6. An edited version of the video for the November 12, 2016 test is attached as Exh. 7, and an edited version of the video for the November 14, 2016 test is attached as Exh. 8. I may choose to rely on all or parts of these videos in my trial testimony

D. The 850 System

[120] Although I cite to the version of the 2040 Manual labeled BRGE00003253, the same disclosures I rely on can be found in the version of the same document produced as BIO-RAD-000001, which was used as Exhibit 6 at the Metrohm deposition. See Metrohm Tr. at 102:11-105:25 (also testifying that there were no major hardware changes to the 2040 System from 2008 until 2015).

- Deposition testimony of Bob Iovanni, Wayne Bland, Farah Mavandadi, and Shawn Anderson.

348. The accused NGC system products do not infringe any of the Asserted Claims of the Asserted Patents. However, to the extent that Plaintiffs contend that the accused products meet every element of an asserted claim, that claim is invalid under Plaintiffs' claim interpretation as anticipated under 35 U.S.C. § 102(g) or at least obvious under 35 U.S.C. § 103.

349. I discuss the NGC Prototype System in Section IX.

VIII. INVALIDITY OF THE ASSERTED PATENTS

A. The '589 Patent Is Invalid in View of the 2040 System Alone or in Combination with the 850 System and/or the 811 System and/or the Agilent 1100/1200 Series and/or Hess and/or the DuoFlow System and/or Wendell

1. Claim 1[a]: An automated liquid chromatography system comprising

350. The 2040 System discloses an automated liquid chromatography system that can be used, for example, for chromatography.

351. The 2040 System discloses a multitude of "wet part modules" that are used for automated liquid handling. (2040 Brochure at BRGE00001521 ("The Applikon Analytical ADI 2040 Process Analyzer is a multipurpose wet chemical analyzer, that has been designed to offer flexibility and withstand the harshest environments. It makes use of proven analytical techniques, like titration, colorimetry and dynamic standard addition with ion selective electrodes.").) Because the software of the 2040 System allows it to run automated functions (*Id.* at BRGE00001522), the system is automated. (*Id.* ("The software allows independent runs for analyses, validation of the results, calibration of the system and cleaning of the sampling device, measuring cell and probes as well as control of external devices such as sample preconditioners. These various runs can be activated via the human interface, but also on time basis, by remote control or by if-statement. Using these options the Analyzer can for example run a calibration and/or cleaning cycle if a result lies outside certain pre-defined limits. Sample streams may be overriden [sic] or reactivated for analysis, by preprogramming, remote control or by if-statement. The Analyzer is able to verify the presence of sample and trigger an alarm when insufficient. It will keep a record of recent analyses, including titration curves and calibration data, to ease trouble shooting.").) These modules allow the system to automatically direct fluid flow to and through a liquid chromatography column.

352. Numerous disclosures in the 2040 System documentation further reinforce the automated nature of this liquid chromatography system. For example, the 2040 System performs automatic calibration and cleaning. (*Id.* at BRGE00001521 "Its rugged hardware and the possibility to do automatic calibration & cleaning, results in a 99.5% up-time.") The 2040

System's "controller makes it possible to run up to 3 independent analyses simultaneously." (*Id.*) The 2040 System performs "[t]itration through a full scan with decreasing burette additions in the vicinity of the inflection point, automatically finding inflection points." (*Id.* at BRGE00001524.) The 2040 System performs differential colorimetry where "[t]he color development stabilization is automatically detected by making use of differential absorbance measurements." (*Id.*) The 2040 System performs an automated method for dynamic standard addition. (*Id.* ("This method has been developed specially to work with ion-sensitive electrodes. A small and precise amount of sample is taken, and buffer will be added. The Analyzer will then do a measurement and instruct the burette to add a calculated amount of standard solution to the mixture. Then it will repeat the measurement. From the difference it will calculate the original concentration.").)

353. The 2040 System consists of up to 20 "wet part modules." (2040 Manual at BRGE00003266.) The wet part modules generally have a collection of tubes that are used to carry fluid between modules as can be seen in the figure below:

(2040 Brochure at BRGE00001521.)

354. The numerous wet part modules have various functions relating to the movement and analysis of a fluid stream. According to the 2040 Manual, "[o]ne wet part can have different functions depending on the wet part configuration. For example, a Valve module can be used as an addition valve to add a reagent into the reaction vessel or as a sample selection valve for sample stream selection." (2040 Manual at BRGE00003305.)

355. As the 2040 Manual explains, the overall system is "controlled by a Computer Board Assembly in combination with an Input/Output (I/O) Module, a Serial module and a Sensor Module. The I/O module controls wet part modules, external devices and the communication with external devices including remote control. The serial module is used to

connect an external computer to perform serial communications. The Sensor Module reads the signals from the connected sensors and convert these to digital values. . . . The Computer Board Assembly drives the human interface and the memory card and uses an internal serial bus for interfacing the I/O Module(s), the Serial modules, the Sensor Module(s) and the burette module(s)." (*Id.* at BRGE00003266-67.) The system also has a memory card and uses a serial bus to communicate with the I/O Modules, the Sensor Modules, the Serial Modules, and the Burette Modules.

356. The 2040 System is a liquid chromatography system. The 2040 Brochure discloses that "Applikon Analytical systems are available using titration, colorimetric analysis, ion selective electrodes or more complex electrochemical analysis techniques such as voltammetry and ion chromatography." (2040 Brochure at BRGE00001527.) A POSITA would have recognized that the 2040 System is one of Applikon Analytical systems that can perform ion chromatography. Further, a POSITA would have recognized that the disclosure of "ion chromatography" is a disclosure that the 2040 System can be used for liquid chromatography. Ion chromatography is a specific type of liquid chromatography that is well known to those skilled in the art.

357. The 2040 System has standard components to perform liquid chromatography. More specifically, the 2040 System has all the components that typically make up a liquid chromatography system: valves, pumps, mixers, and sensors.

358. Specifically, the 2040 System discloses a Solenoid Valve Module that can have one or two plunger valves and be used as a sample, liquid addition, or drain valve. (2040 Manual at BRGE00003307.) The 2040 System discloses a Macro Pipette Module that can be used with the 2/2 or 3/2 Valve Modules to provide sampling. (*Id.* at BRGE00003308.) The 2040

System discloses Tubing Pump Modules that come in multiple configurations and can provide flow rates of 5, 40, 120 or 320 ml/minute. (*Id.* at BRGE00003309.) There is a constant speed pump with an AC motor, and one with a DC motor that has a peristaltic pump head. (*Id.*) These modules are used for adding reagents, sample or rinse solutions, for carrying sample from the Sampling System Loop Module or draining the reaction vessel. (*Id.*)

359. The 2040 System discloses a Burette Valve Module that has a rotary type of valve with five hydraulic connections. (*Id.* at BRGE00003310.) It can be used in a variety of different configurations. (*Id.*) The 2040 System discloses a Burette Selector Valve Module that has ten hydraulic connection ports and is a rotary type valve. It can be used for sampling, reagent addition and rinsing. (*Id.*) The 2040 System discloses a Burette Module that consists of a cylinder and motor controlled piston. (*Id.* at BRGE00003311.) This configuration allows the cylinder to be filled and the contents dosed. (*Id.*) This module is very flexible and can be combined with a number of other modules. (*Id.* at BRGE00003312-15.)

360. The 2040 System discloses a Sampling System Loop Module that can be used for highly reproducible closed loop sampling. (*Id.* at BRGE00003317.) It can be used in its 3 way or 2 way configuration and in conjunction with valves pumps or burettes. (*Id.*)

361. The 2040 System discloses a Stirrer/Vessel Holder Module used to stir or mix a sample. (*Id.* at BRGE00003306.)

362. The 2040 System discloses a Cuvette Module that can be used to detect light absorbance of the sample coming off the column. (*Id.* at BRGE00003322.) This module has a number of different light sources and a number of different filters that can be used to detect light of different wavelengths. (*Id.* at BRGE00003323.) Samples in the module may be stirred using a magnetic stir bar. (*Id.* at BRGE00003322.) The 2040 System discloses a Basic Probe

Colorimeter Module to detect the wavelength of light which can indicate the presence of particular components coming off the column. (*Id.* at BRGE00003326.) The 2040 System discloses a sensor to measure the conductivity of a solution and a sensor to measure pH. (*Id.* at BRGE00003371, -3373.) There is also a sensor to measure temperature. (*Id.* at BRGE00003371-3372.)

363. Since the 2040 System is designed to deliver automated fluid flow to a variety of different devices and has all the components necessary to deliver such flow to a chromatography column, it meets all the elements of this claim. During his deposition, Metrohm witness Mr. Koshy testified that the 2040 System included pumps that can provide controlled delivery. Metrohm Tr. at 91:5-92:4. Mr. Thomas Koshy further testified that the 2040 System was capable of performing chromatography—it included all the components needed to accomplish chromatography such as the sample loop and a pump, and readily available columns could be included or connected with the 2040 System. *Id.* at 143:20-144:15; 161:23-162:9; 243:8-244:12.

364. To the extent the 2040 System does not anticipate claim 1 because it is not considered a liquid chromatography system, it would have been obvious in light of the 2040 System and the knowledge of a person of ordinary skill in the art.

365. As I testified at the PI hearing in the SDNY case, the 2040 System was designed to deliver controlled fluid flow to various components. There would be no reason to argue that one of those components would not be a chromatography column, and it would take about two minutes to hook a column up to the 2040 System. A POSITA would have motivation to use the 2040 System for such an application because it is automated, can be programmed, and already has all the necessary components to perform chromatography.

366. Moreover, a person of ordinary skill in the art knowing the modular liquid chromatography systems already available to the public would be motivated to use the 2040 System to perform liquid chromatography because it has all the necessary components. Multiple prior art systems disclose the use of chromatography with systems having the same modular components as the 2040 System. For example, the Metrohm 850 Professional IC System is an automated Ion Chromatography system, as discussed below in my discussion of the 850 System for '589 claim 1. *See, e.g.*, Cation Prep 1 Manual at 4, 10-14; AnCat Manual at 4-5. The Metrohm 811 Online Ion Chromatograph is an automated Ion Chromatography system. *See infra* § VIII.A.1.(a); *see also* 811 Online IC Instructions for Use at 6. The NGC Prototype System is an automated liquid chromatography system, as discussed below in my discussion of the NGC Prototype System for '589 claim 1. *See, e.g.*, [redacted]. Bio-Rad's DuoFlow system is a modular chromatography system used for "high resolution purification of proteins, peptides, and other biomolecules." DuoFlow Manual, p. 1-1; *see infra* § VIII.A.1.(b).

367. A person of ordinary skill in the art would have been motivated to use such teachings to perform liquid chromatography with the 2040 because the prior art systems each deal with modular design systems that perform liquid chromatography. Such a modification would simply apply one of a finite number of well-known techniques in a predictable manner, to achieve well-known, predictable results. This is confirmed by the testimony of Mr. Koshy, who testified that the 2040 System as sold could be used for liquid chromatography, as it had all the components needed to do so. Koshy Decl. ¶ 8; Metrohm Tr. at 143:44-144:15, 161:23-163:1, 233:18-234:8, 243:8-244:12.

368. Bio-Rad has acquired a 2040 System that performs automated liquid chromatography and contains the modules described in the 2040 Manual. I have performed tests that show the 2040 System can deliver controlled fluid flow to and through a liquid chromatograph column and which I consider an automated liquid chromatography system capable of performing liquid chromatography. The tests are described in the test report, attached as Exh. 4. I recorded videos of these tests showing the 2040 System performing liquid chromatography. A video of the test conducted on November 12, 2016 is attached as Exh. 5 and a video of the test conducted on November 14, 2016 is attached as Exh. 6. An edited version of the video for the November 12, 2016 test is attached as Exh. 7, and an edited version of the video for the November 14, 2016 test is attached as Exh. 8.

(a) The 2040 System in Combination with the 811 System

369. To the extent the 2040 System is found not to disclose an automated liquid chromatography system, this element would be obvious in light of the 2040 alone or in combination with the 811 System which discloses this limitation.

370. For example, the 811 System discloses an automated liquid chromatography system used, for example, for ion chromatography. (811 Instructions at 6.) "The Metrohm 811 Online Ion Chromatograph is designed to provide continuous sample analysis in a process environment." (811 Instructions at 6.) The 811 System can be custom-tailored to fit most ion chromatography applications. (811 Instructions at 6 ("The 811 can be custom-tailored to fit most IC applications. The single-channel instrument allows either anions or cations to be analyzed. The dual channel version is normally used to analyze anions and cations simultaneously, and is housed in the single channel cabinet.").)

371. The 811 System is automated using a built-in PC, which can call up and execute calibration procedures or different sample sequences. (811/821 Brochure at 5 ("With a freely

DATED: September 14, 2020

Bruce K. Gale, Ph.D.

EXHIBIT I

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

Cytiva Sweden AB et al.,

Plaintiff,

-against- Civil Action No. 18-1899-CFC

Bio-Rad Laboratories, Inc.,

Defendant.

VIDEO-RECORDED DEPOSITION OF
KEVIN PETERSEN
Zoom Recorded Videoconference
11/18/2020
1:37 p.m. (CST)

REPORTED BY: AMANDA GORRONO, CLR
CLR NO. 052005-01

DIGITAL EVIDENCE GROUP
1730 M Street, NW, Suite 812
Washington, D.C. 20036
(202) 232-0646

11/18/2020

1:37 p.m. (CST)

VIDEO-RECORDED DEPOSITION OF KEVIN PETERSEN, held virtually via Zoom Videoconferencing, before Amanda Gorrono, Certified Live Note Reporter, and Notary Public of the State of New York.

APPEARANCES
(Via Zoom Videoconferencing):

ON BEHALF OF PLAINTIFF Cytiva Sweden AB et al.:
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ALSO PRESENT:
Sean Damon, Esquire, Quinn Emanuel Urquhart & Sullivan LLP
Andy Mortensen, Legal Videographer, Digital Evidence Group

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EXHIBITS

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get the device, you know, physically in the location (inaudible) power supply figured out.

I think that, you know, the actual -- during the bulk of the testing happened in probably about a 39-hour time frame. It probably took -- at least in my time. I don't know Travis's time, but it was probably about -- about 40 hours worth of work. With the actual -- once you figured out what the system is actually doing, and you just want to try and run some tests. So it was not a lot.

Q. So when you say -- when you're estimating that 40 hours, what steps were done in those 40 hours?

A. Again, this is where I have to compare what my notebook says relative to when I submitted times to Dr. Gale. So I would suspect that steps that were probably done in that were, one, figuring out how to do the gradients, how to actually pump it, verify that it does pump it, get the programming all done, and actually have it do chromatography and see if it separated anything.

So the bulk of the steps were

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probably done in -- at least in the terms of the time I spent. I don't know about Travis's hours.

Q. Were you provided any documents with the 2040 System?

A. So, I looked for the manuals, because I thought sure we had a manual. But I didn't see any electronic copies of manuals in the documents I provided, so I must have been given a hardcopy manual. So either Travis or I would have followed the hardcopy manual, or even Travis may have hardcopy manual. Travis may have found an electronic manual, but I believe we worked off of a hardcopy manual that came with the instrument.

Q. Were there any other documents that you operated off of?

A. No.

Q. So what was Dr. Gale's role in the Applikon Project?

A. So, he -- he came to us, like I mentioned, and said we'd like you to make this do chromatography. We would give him occasional updates and say this is where we're at, these are the

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problems we're having.

And let's see, later he -- I think we came to him at one point and said we were able to get to do chromatography, and here's some of our data. He's like great, the lawyers would like you to film it now. So okay. So I think we filmed it at some point and said okay, now the lawyers would like you to switch components. So okay, so we moved this to there and that to there. And so we filmed that we could switch it too.

That's -- as far as I remember, that's mostly what -- I think I asked him later, you know, should I go this direction or that direction? He said he didn't think those issues were necessary just yet, or at all. Mostly we just waited for him for general directions as to what he wanted us to do, and we were able to do it.

Q. And you weren't given direction by anyone else?

A. No.

Q. So is if fair to say that the only people involved in the Applikon Project were -- would

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be you, Mr. White, and Dr. Gale?

A. Yes.

Q. Okay. Did you read the entire hardcopy 2040 manual that you mentioned before?

A. No, certainly not.

Q. Do you know what parts of it you read?

A. We would have read the parts related to programming it, we would have read parts related to hardware-specific questions we may have had. I -- I don't remember. Again, this is four years ago since I've even, you know, seen this.

Q. Did you find any sections of the manual that specifically discuss liquid chromatography?

A. It's been too long since I've actually had a manual in front of me to answer that question. I don't know.

Q. Did you find any instructions in the manual for using the 2040 System to perform ion chromatography?

A. Again, I don't remember that one

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THE TECH: (Complying.)
Q. All right. Let's focus on the program titled chrom test2. So you believe that you and Travis White created the program chrom test2, correct?
A. Yes.
Q. Would that program have been entered through the interface shown in this photo of the 2040 System?
A. Yes.
Q. Who would have entered it?
A. Travis primarily, and then I would have also entered things as well.
Q. Who would have been present while you and Travis were entering all the steps in this program?
A. Just Travis or I.
Q. And how long would that have taken?
A. I don't remember, unfortunately. It didn't seem like it took too long, but it was a very bold interface, and so it wasn't as easy as just typing in a value. You had to literally go through

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and add each one.
Q. Do you have an estimate on how long it took?
A. I -- unfortunately, I'm not the best person to ask on the estimate of time, simply because it's so long ago. But it does -- it was not -- it didn't seem like it took an unreasonable amount of time.
Q. Would have that been recorded in the timesheet that you provided to Mr. Bilsker and Mr. Damon?
A. The time that it spent to physically stand up the instrument and program in the inputs? Is that the question?
Q. Yes.
A. No. It wouldn't be reflected there.
Q. Okay. How many inputs were required to create the program chrom test2?
A. I don't remember. But the program is on the instrument, so you can see for yourself.
Q. Were there any documents used as a reference during the programming of chrom test2?

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A. The manual I'm sure Travis would have used.
Q. Were there any notes referred to during the programming of chrom test2?
A. Again, it would have been in Travis's notebook.
Q. Okay. Were there any flow charts created when programming chrom test2?
A. No. Not that I'm aware.
Q. And so was chrom test --
MR. SEBBA: Withdrawn.
Q. Was the program chrom test2 run as part of the Applikon Project?
A. Yes.
Q. By whom?
A. By myself and by Travis.
Q. And what were the results?
A. That we were able to put a dye into a chromatography column automatically hands off, and then change the gradient across that chromatography column, and then dilute the individual dyes in almost a baseline fashion. In other words, it worked very

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well. It was also very reproducible. Every time we run that it gave very reproducible values in terms of the times the dyes came off, and just the order of things like that. It was very reproducible.
Q. How many times did you run that experiment?
A. I think two or three. I'd have to look at the final report.
Q. Do you remember when you first were able to run that experiment?
A. Not exactly. And when you say "that experiment," you remember there's a -- there's an iterative process, right? Where you run it and say, do I need to change the program at all? If it works, then you say, okay, that's good, and you don't touch the program anymore.
Q. Approximately how many iterations of this program did you create in the Applikon Project?
A. I don't know. If you were to look at the actual panel and say, oh, all of those are different programs and how many iterations were there? It depends on what you call an iteration.

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SIGNATURE PAGE
Case: Cytiva Sweden AB, et al. v. Bio-Rad Laboratories, Inc.
Witness Name: Kevin Petersen
Deposition Date: November 18, 2020

I do hereby acknowledge that I have read and examined the foregoing pages of the transcript of my deposition and that:

(Check appropriate box):
( ) The same is a true, correct and complete transcription of the answers given by me to the questions therein recorded.
( ) Except for the changes noted in the attached Errata Sheet, the same is a true, correct and complete transcription of the answers given by me to the questions therein recorded.

_____ _____
DATE WITNESS SIGNATURE

_____ _____
DATE NOTARY

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ERRATA SHEET

Case: Cytiva Sweden AB, et al. v. Bio-Rad Laboratories, Inc.
Witness Name: Kevin Petersen
Deposition Date: November 18, 2020
Page No. Line No. Change

_____ _____
Signature Date

EXHIBIT J

Test Report 11-14-16

We performed a chromatography separation of 5 food dyes simultaneously on the Applikon instrument. The separation was complete and appeared to be a baseline separation between the dyes. The separation results were also reproducible with the centers of each of the dyes eluting at the same times. Each test was performed on different days spanning an 11 day period. The results were also reproducible after switching the positions of two of the fluidic components within the Applikon instrument.

Instrument Programming Details

The goal of the programming was to reproduce the steps of a dye chromatography experiment. The shared stirrer for PBS and methanol mixing was the sole supply of fluid to the 5mL/min peristaltic pump that was pumping the elutant through the C18 chromatography column. Figure 1 shows all the various pumps, valves and stirrers that were programmed to perform the experiment, the names on the labels will be used throughout the programming description. All the programming was performed on the instrument using the built-in keypad and function buttons. Any pump or valve that is not labeled in the figure was not required for the chromatography experiments that we performed.

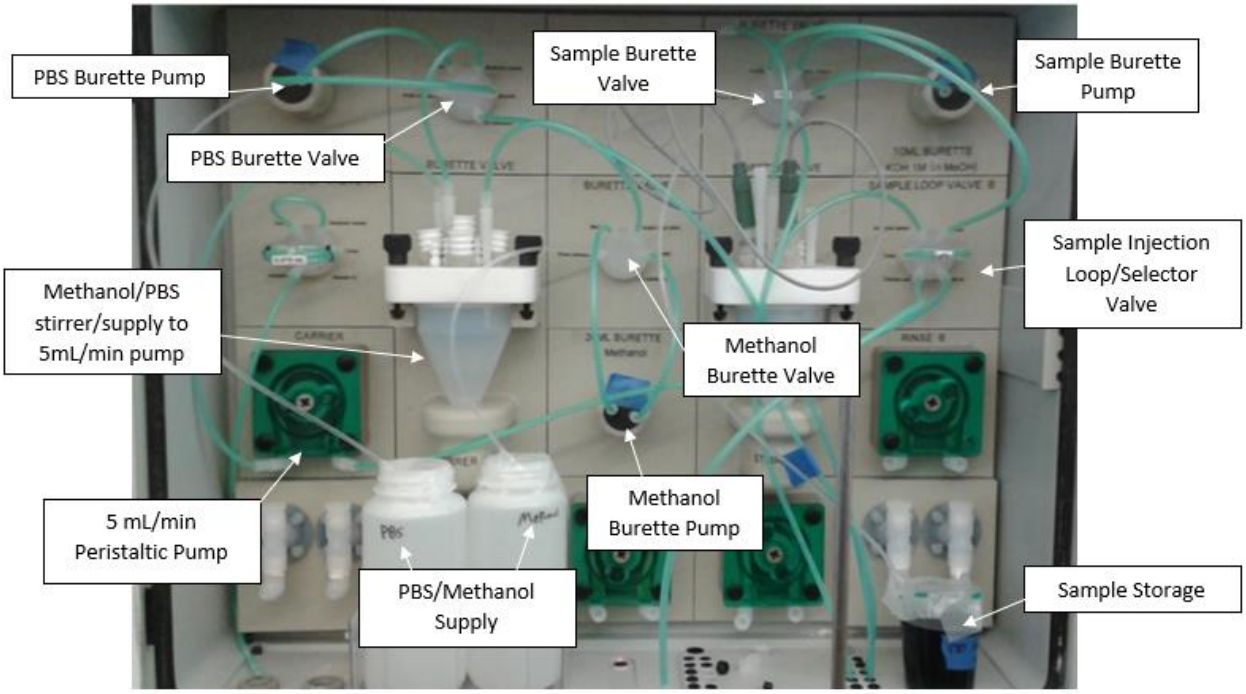

Figure 1. Initial layout of fluidic components in the Applikon instrument for performing chromatography in Tests A, B, and C.

The first step in the program was a flush of the sampling column using 100% methanol to ensure that all contaminants were flushed out of the column. To perform the flush 40 mL of methanol was pumped from the methanol supply into the stirrer/supply reservoir using the methanol burette pump. Due to the 20 mL capacity of the burette, this required the burette to fill and dispense twice. After the methanol was pumped into the supply reservoir, the 5mL/min peristaltic pump was switched on and the methanol was drawn from the reservoir and pumped to the sample injection valve which was set in the

"on" position. In the "on" position the fluid from the peristaltic pump bypasses the sample loop itself and flows straight into the chromatography column.

After pumping pure methanol through the column, the next step was to return the fluid in the column to 50% PBS. This was easily achieved by adding 30 mL of PBS and 15mL of methanol to the reservoir which had 15mL of methanol remaining after flushing the column. Of the 60 mL of the 50/50 methanol mix, 45 mL was pumped through the column (the equivalent of three times the volume of the column). After the 50/50 mix was pumped through the column, the next step was to return the fluid in the column to 100% PBS before adding the sample. This was achieved by adding PBS to the stirrer 15mL at a time six times while the peristaltic pump continued to pump through the column. The result of this step left the fluid in the column as <1% methanol, which we considered to be acceptably close to 100% PBS for our purposes.

While the column was being returned to 100% PBS the sample was prepared for injection into the column by pumping 10 mL of the dye into the sample loop selector valve using the sample burette pump. The volume of the loop is only 0.5 mL however a much larger volume was pushed through the loop to ensure that the sample loop contained only the sample. The sample loop is filled while the valve is in the "on" position. In the "on" position, fluid pumped by the sample burette flows through the sample loop and passes directly to the sample waste reservoir. Once the sample was pumped into the loop and the column was filled with 100% PBS, the loop valve was switched to the "off" position. This allowed the 5mL/min peristaltic pump to pump the elutant through the sample loop to push the sample in the loop into the column. The elutant at this point was changed to 10% methanol by adding methanol and PBS to the stirrer while the peristaltic pump was switched "off".

The next phase of the experimental program was the methanol gradient, which incrementally increased the concentration of methanol from the starting concentration of 10% to the final concentration of 75% over 40 minutes. To ensure the correct concentrations, the starting volume of 10% methanol was fixed at 40mL and that volume was maintained throughout by adding 5mL of a combination of PBS and methanol every minute to compensate for the amount being pumped every minute by the peristaltic pump.

After the completion of the methanol gradient the methanol concentration was increased to 100% by adding methanol to the stirrer 15mL at a time while continuing to run the peristaltic pump. This was repeated several times until the concentration of methanol was sufficiently high to ensure that all contaminants were flushed from the column and the fluid in the column was 100% methanol. At this point, the flows were turned off and the cap was placed over the exit of the column to store it until the next test.

Flow Path Description

The flow path of the various fluids through the instrument are shown in the following figure. The color code for each fluid is as follows: Green is used to show the flow path of the pure PBS, red is used to show the flow path of pure methanol, orange is used to show the flow path of the elutant which can be PBS, methanol or some combination of the two depending on the point in the chromatography program and black is the sample flow path of the sample when the sample loop valve is in the "on" position (the only difference in the "off" would be that the loop itself would be orange instead of black indicating that the elutant from the peristaltic pump is flowing through the loop). The blue arrows in the figure are

used to show the direction of the flow in each piece of tubing. It should be noted that any piece of tubing that is not one of the colors mentioned above is not used in this experiment.

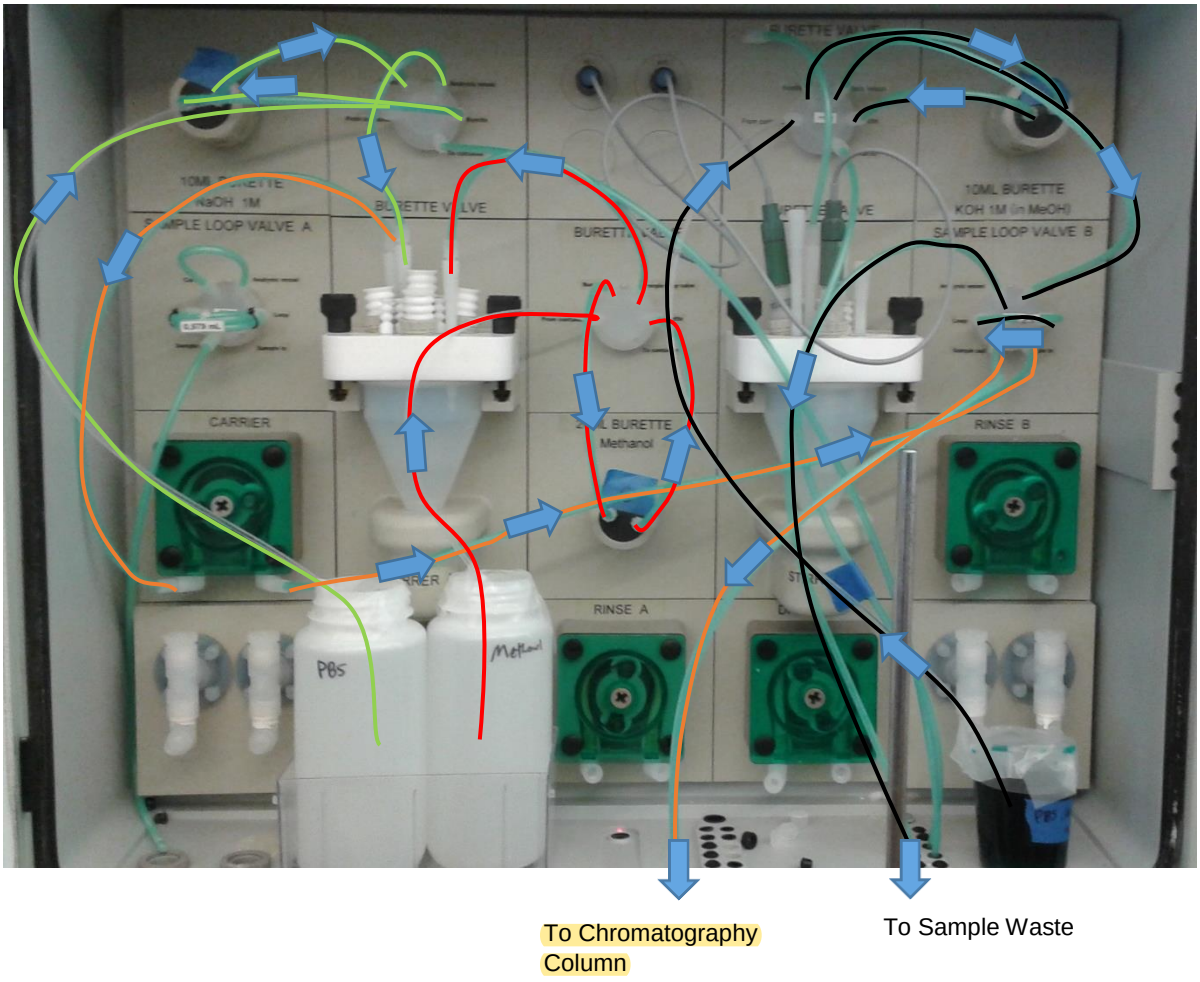

Figure 2. Instrument Flow Path Diagram

Chromatography

The initial sample was a combination of 5 food dyes dissolved in 1X PBS buffer at pH 7.3. The first test used a sample with small and varying concentrations of each dye. In the second test, each dye was .02% in 1X PBS by weight (See Table 1). We programmed the Applikon instrument to prepare the column with a variety of flushes, then load the mixed sample, and finally gradually increase the percent methanol in the elutant buffer for a completely automated process with no hands-on processing. Specifically, we used one burette pump with sample loop to inject a precise amount of sample to the column. We used the other two burette pumps and valves to add varying amounts of methanol or 1X PBS to the stirrer/supply vessel. The stirrer/supply vessel mixed the incoming volumes to produce a smooth steady gradient that was continuously pumped out through the peristaltic pump, and through the sample loop valve to the column. We collected the fractions off the column manually because we did not have an autosampler to collect them for us. The name of the routine that we programmed using the display and interface that was provided native to the Applikon instrument was called “chrom test2”

All components used came with the Applikon instrument as it was delivered to us. The device is designed to suit particular processes and applications and as received it was suited for higher flow rates than we needed. We purchased a different peristaltic pump from Applikon that was rated for smaller flows to make it more compatible with lab-scale chromatography systems. We also used new peristaltic tubing since we did not know the condition of the peristaltic tubing itself. To perform the chromatography, we used a common C18 chromatography column (Biotage part # FSL0-1118-0012), and an adapter (Idex Health& Science part # P-650) to connect the tubing from the Applikon instrument to the column. All food dyes were purchased from (Flinn Scientific part # AP7375).

The hands-off program clearly separated the 5 food dyes from each other with what appears to be a baseline separation between them. Test A was performed on 11-3-16 with a mixture containing only a small concentration of each of the food dyes, then in Test B (performed 11-4-16), the concentration of mixed food dyes was increased for better visibility in the photographs and also to show reproducibility. Test C (11-11-16) was a repeat of Test B, and was filmed from start to finish. In Test D (11-14-16), several physical components of the Applikon system were switched relative to the previous 3 tests. Specifically, the "sample loop valve B", and the "rinse B" peristaltic pump were switched and also the "carrier" peristaltic pump, and the "sample loop valve A" were switched in the instrument. After switching these components, and the same chromatography was performed a 4th time. Test D showed that two of the various subcomponents could be easily switched in about 10 minutes time, and the chromatography results after the switching were unaffected. The entire chromatography separation process was filmed for Test C. The switching of the "carrier" peristaltic pump, and the "sample loop valve A" and the immediate Test D that followed was also filmed.

In Tests A, B, C, and D the vials were numbered and collected at the same time so that the vial number would be directly comparable in each of the other tests. Because manual collection times were not identical for each collected tube (some were 50 seconds and others 60 etc.), some tubes ended up with more volume than can be capped without spilling. Capping was useful to photograph all the eluted dyes in a single image so some of the liquid from the tops of some tubes was poured or pipetted out to allow capping and subsequent photographing. Below is a summary of the results shown in Table 1 and Figures 3-6. The results are quite reproducible with each of the 5 colored peaks eluting at the same times in all four tests.

Table 1 Description of individual dyes present in the separated mixture and listing the vial and corresponding elution time for each dye present.

	Test A mixture (initial wt. % dye in 1X PBS)	Test B mixture (initial wt. % dye in 1X PBS)	Test C mixture (initial wt. % dye in 1X PBS)	Test D mixture (initial wt. % dye in 1X PBS)	Center of peak (vial #)	Center of peak elution time (minutes)
Yellow 5	0.0077	0.02	0.02	0.02	6-7	51.1
Yellow 6	0.0084	0.02	0.02	0.02	14-15	58.1
Red 40	0.0024	0.02	0.02	0.02	18-19	101.6
Blue 1	0.0038	0.02	0.02	0.02	24-25	107
Red 3	0.002	0.02	0.02	0.02	34-35	116.5

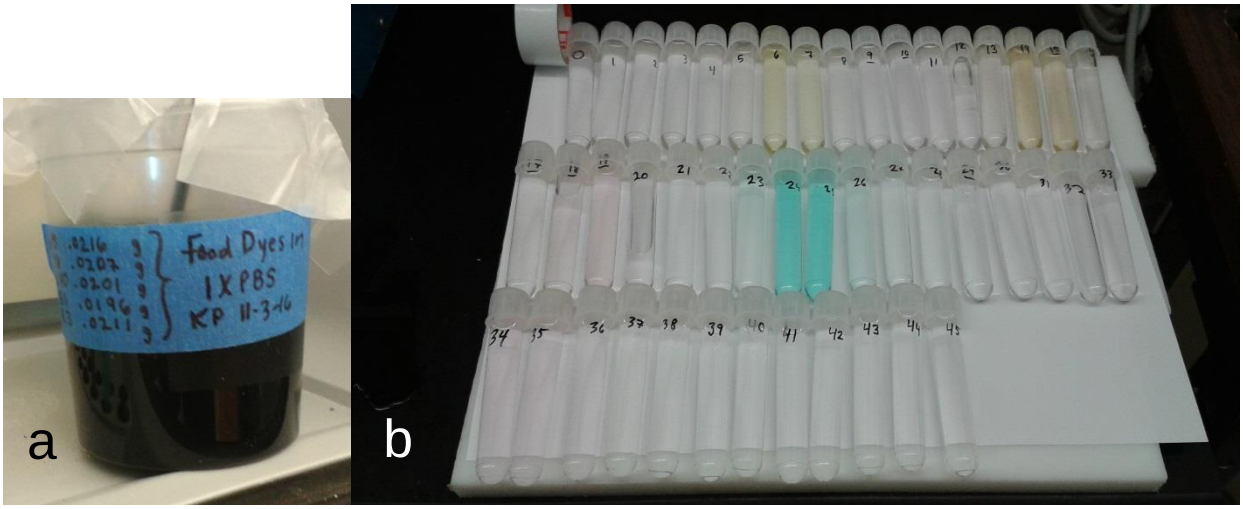

Figure 3. Test A at low dye concentration. a) starting mixture of dyes. b) separated dye by fractions collected. The centers of each peak of eluted colors were at vials 6-7, 14-15, 18-19, 24-25, 34-35.

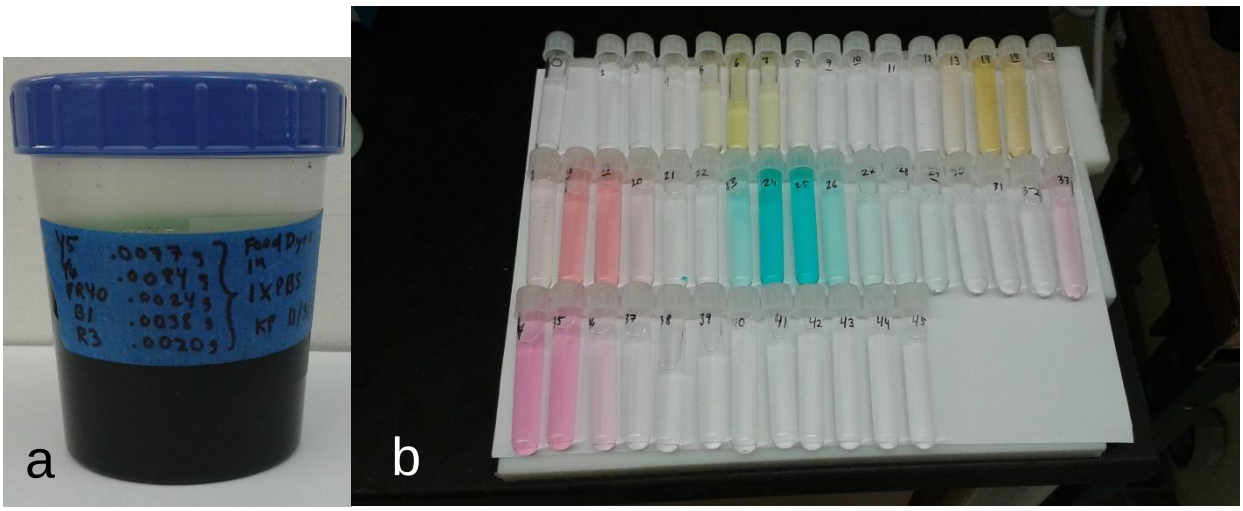

Figure 4. Test B at higher dye concentration. a) starting mixture of dyes. b) separated dye by fractions collected. The centers of each peak of eluted colors were at vials 6-7, 14-15, 18-19, 24-25, 34-35.

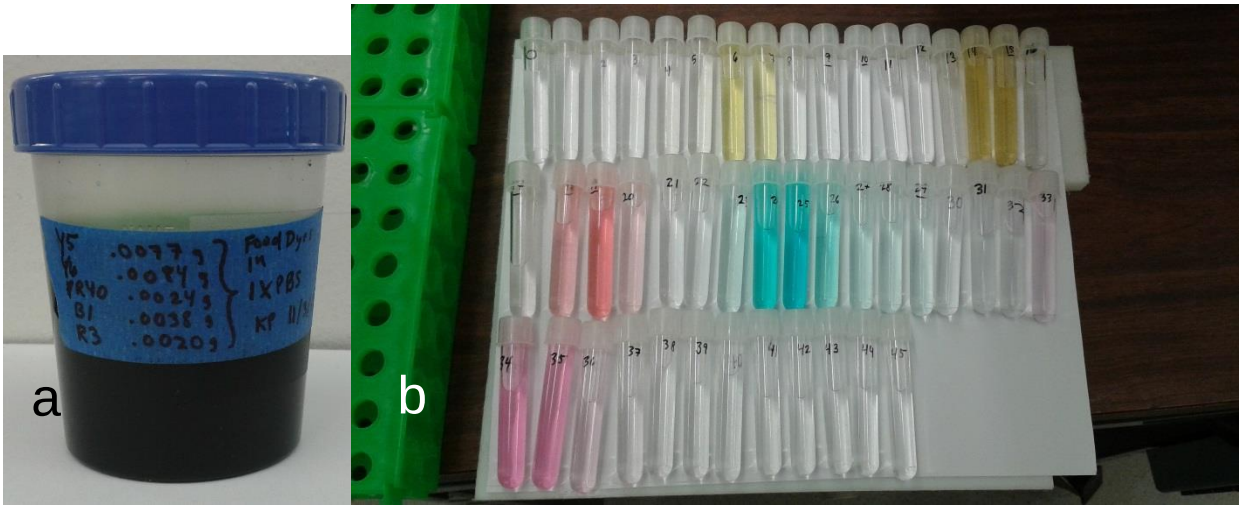

Figure 5. Test C at higher dye concentration. a) starting mixture of dyes. b) separated dye by fractions collected. The centers of each peak of eluted colors were at vials 6-7, 14-15, 18-19, 24-25, 34-35.

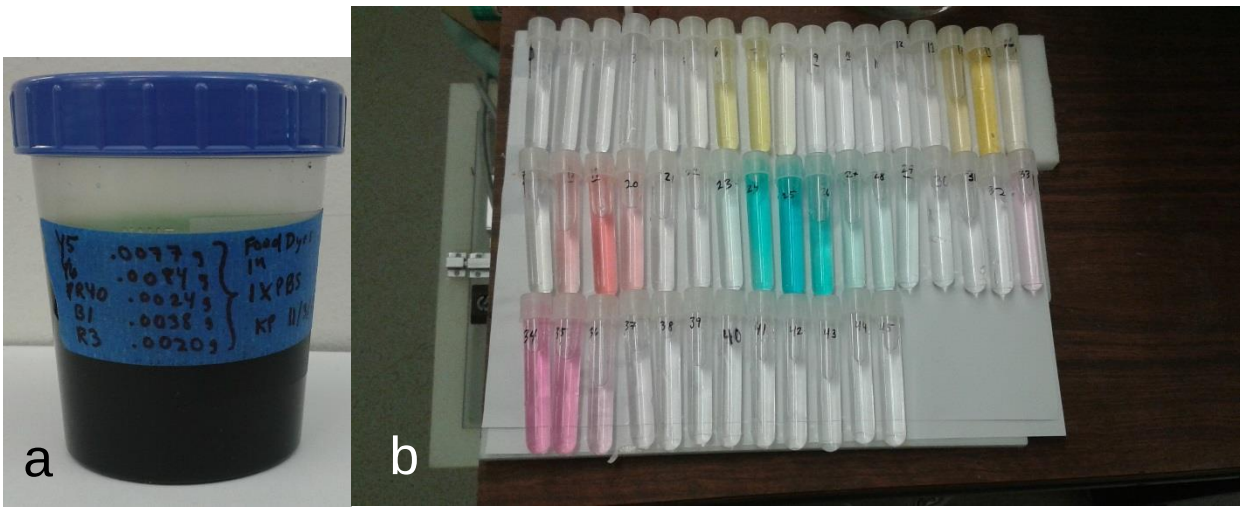

Figure 6. Test D at higher dye concentration and after switching instrument components. a) starting mixture of dyes. b) separated dye by fractions collected. The centers of each peak of eluted colors were at vials 6-7, 14-15, 18-19, 24-25, 34-35.

The colors of each individual dye as diluted in 1X PBS match the hues found in the fractions collected after chromatography. Each dye also elutes in the order expected based upon the results of others who have separated food dyes on C18 columns under similar conditions.

Figure 7. Individual dilutions of dry dye powders in 1X PBS from left to right: FDC Yellow #5, FDC Yellow #6, FDC Red #40, FDC Blue #1, FDC Red #3.

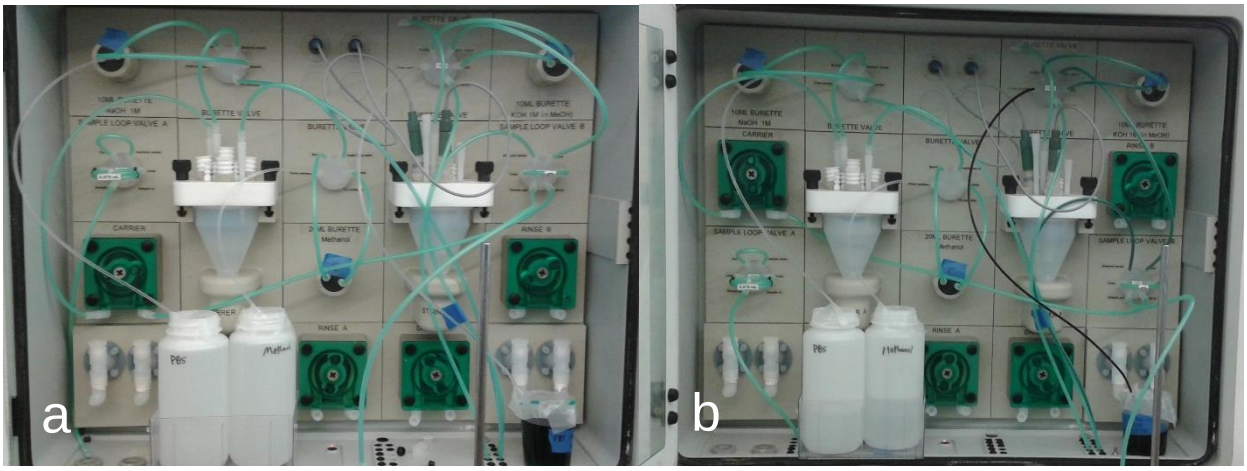

Figure 8. Fluidic components for chromatography. a) layout for the first three tests (Tests A, B, C). b) layout for the last test (Test D). Note the switched location of “carrier” peristaltic pump, and the “sample loop valve A”. We also switched the location of “rinse B” peristaltic pump and “sample loop valve B” but this was not filmed.

EXHIBIT K

UNITED STATES DISTRICT COURT

DISTRICT OF DELAWARE

Case No. 18-1899-CFC

CYTIVA SWEDEN AB, and GLOBAL LIFE SCIENCES SOLUTIONS USA LLC,

Plaintiffs,

v.

BIO-RAD LABORATORIES, INC.,

Defendant.

REMOTE VIDEOCONFERENCED AND

VIDEOTAPED DEPOSITION OF

STEVEN WERELEY, PhD

DATE TAKEN: NOVEMBER 20, 2020

REPORTED BY: PAUL J. FREDERICKSON, CSR

JOB NO. 4343717

"Fundamentals and Applications of Microfluidics." 07:16:28 07:16:30
Q. And does that have a number of different editions? 07:16:32 07:16:34
A. Yes, it does. 07:16:35
Q. Did you write the chapter or the few sentences on liquid chromatography in that textbook? 07:16:37 07:16:40 07:16:42
A. Well, it was a collaborative effort, so I certainly, you know, contributed to writing it. I don't know which words exactly I wrote and which words I didn't. And there is also, in addition to the text portion of that section on liquid chromatography, there's a few examples. And, you know, so we sort of traded around/circulated these drafts and everyone commented. 07:16:43 07:16:46 07:16:51 07:16:53 07:16:56 07:16:58 07:17:06 07:17:08 07:17:12 07:17:14
Q. Yeah. So that -- sorry, that wasn't the question. 07:17:15 07:17:16
Did you actually write -- so when you wrote the textbook, I assume certain people had primary responsibility for certain chapters. Is that fair? 07:17:17 07:17:19 07:17:21 07:17:22
A. That -- yeah, that's fair. 07:17:26

Q. Did you have primary responsibility for the liquid -- for the chromatography chapter? 07:17:27 07:17:29 07:17:30
A. I guess I would say I didn't -- I wasn't primarily responsible for writing that chapter but we all contributed to editing that chapter. 07:17:33 07:17:34 07:17:37 07:17:40
Q. Yeah. So let's just see if we can stick with the questions and we'll probably get done a lot quicker. That again wasn't the question. 07:17:41 07:17:43 07:17:45 07:17:49
Why was it that you didn't have primary responsibility for the chromatography section? 07:17:49 07:17:52 07:17:53
A. We divided up the topics in the book, and, you know, everybody took different topics, and this was not on my list. 07:17:57 07:17:59 07:18:01 07:18:04
Q. So was it just you threw the topics in the air and wherever they landed that's what you got to write? Or was it divided up based on experience? 07:18:05 07:18:07 07:18:10 07:18:12
A. It was -- we divided the topics up based on who wanted to write or contribute to each section. 07:18:16 07:18:19 07:18:23

Q. So you decided that you didn't want to write the section on chromatography; correct? 07:18:27 07:18:29 07:18:32
A. I decided that I would rather write other sections. 07:18:35 07:18:38
But I guess I have to come back to the fact that everyone contributed to all of the sections that we wrote. 07:18:42 07:18:45 07:18:46
Q. What is it about working on automated fluid handling systems that gives you any type of experience to opine on liquid chromatography systems? 07:18:52 07:18:54 07:18:56 07:19:01
A. Liquid chromatography systems are a form of fluid handling systems. 07:19:05 07:19:06
Q. Right. 07:19:11
But your work on automated fluid handling doesn't give you expertise in automated liquid chromatography systems; correct? 07:19:13 07:19:16 07:19:18 07:19:20
A. I would say -- so I was trained on liquid chromatography in graduate school, and over the years since then I've used liquid chromatography in several projects. 07:19:21 07:19:25 07:19:29 07:19:32
Q. When you say you were "trained on liquid chromatography in graduate school," explain to me what you mean by that. 07:19:36 07:19:38 07:19:40 07:19:42
A. I was trained to use a liquid chromatography system, you know, in the course of my research in graduate school. 07:19:44 07:19:47 07:19:50
Q. What does that mean? You read a book? You watched a video? 07:19:53 07:19:55
A. Both read a book as well as, you know, hands-on experience. 07:19:59 07:20:03
Q. What did you use liquid chromatography for in graduate school? 07:20:05 07:20:07
A. It was largely, I would say -- largely the case that we used liquid chromatography to -- well, I was trained in liquid chromatography in order to -- in -- let's say in anticipation of the need to use it in my research. 07:20:09 07:20:13 07:20:15 07:20:21 07:20:27 07:20:31
Subsequently we didn't need to use that, didn't need to go that way in my research project. 07:20:34 07:20:35 07:20:38
Q. So when you say you were "trained," tell me what that means. 07:20:39 07:20:40
A. You know, I guess that -- that covers the -- learning the theory of liquid chromatography and then learning the 07:20:45 07:20:46 07:20:51

practice of liquid chromatography. 07:20:52
Q. So learning the theory is like 07:20:55
reading something. Is that fair? 07:20:57
MR. MILLER: Objection, 07:20:59
foundation. 07:21:00
BY MR. BILSKER: 07:21:00
Q. What did you mean by "learning 07:21:02
the theory"? Tell me exactly what you did 07:21:03
as far as learning the theory. 07:21:07
A. I was reading passages in 07:21:08
textbooks and, you know, performing some 07:21:10
calculations, things like that. 07:21:14
Q. What kind of calculations were 07:21:16
you performing? 07:21:17
A. Flow-rate calculations, 07:21:20
pore-size calculations, things like that. 07:21:23
Q. Why would you have to do that? 07:21:24
A. To understand how the liquid 07:21:27
chromatography was performing. 07:21:30
Q. To understand how liquid 07:21:35
chromatography was performing, you had to 07:21:36
perform pore size and flow-rate 07:21:39
calculations? Explain that to me. 07:21:43
A. You have to do -- you have to do 07:21:46
some calculations in order to understand how 07:21:47

to set up the liquid chromatography system. 07:21:49
Q. Oh, so you weren't using an 07:21:53
automated liquid chromatography system then? 07:21:55
A. These -- so this was in the 07:21:58
'90s, and it was a much older system. So I 07:22:01
guess I would say it was automated in that 07:22:07
there were sensors and pumps and, you know, 07:22:10
a column and valves and all of that. So, 07:22:14
yeah, I guess I would characterize it as 07:22:19
automated liquid chromatography. 07:22:24
Q. Well, how could it be automated 07:22:25
if you had to do calculations? 07:22:27
A. I guess there are always -- 07:22:34
there are always calculations required when 07:22:36
you're doing, you know, engineering 07:22:37
measurements and things like that. 07:22:39
Q. So what kinds of calculations 07:22:40
are always required using an automated 07:22:42
liquid chromatography system? 07:22:45
A. So flow-rate calculations, 07:22:47
pore-size calculations, things like that. 07:22:53
Q. So are you telling me, are you 07:22:55
telling the jury, that in an automated 07:22:57
liquid chromatography system you don't just 07:22:59
put the sample in and tell the machine "run 07:23:01

chromatography"? 07:23:04
A. I'm telling you about the system 07:23:04
that I was trained on in the '90s. 07:23:06
Q. Well, so in an automated liquid 07:23:08
chromatography system, is it your 07:23:11
understanding or your opinion that you just 07:23:13
put the sample in and tell the machine "run 07:23:15
chromatography"? 07:23:19
A. Could you tell me the time frame 07:23:20
that you're talking about? 07:23:23
Q. Today. 07:23:24
A. Okay. 07:23:24
So these days, yeah, the number 07:23:27
of calculations required are relatively few. 07:23:29
But you still have to, let's say, choose the 07:23:34
right column for -- for your application. 07:23:37
Q. So when you say you "choose the 07:23:41
right column," you don't just tell the 07:23:43
machine what you're planning to separate and 07:23:45
the machine just doesn't do it on its own? 07:23:47
A. It depends on the machine. 07:23:52
Q. So which machines do it on their 07:23:54
own? 07:23:56
A. I've -- I guess I can't comment 07:23:58
on the machines and model numbers at this 07:24:00

point. 07:24:02
Q. Well, you just said it depends 07:24:02
on the machine, so tell me which machine it 07:24:04
does and which machine it doesn't. 07:24:07
A. I can't provide you with an 07:24:09
exhaustive list. 07:24:11
Q. Give me some examples. I don't 07:24:12
want an exhaustive list. Give me some 07:24:15
examples. 07:24:18
A. I can't recall at this point. 07:24:18
Q. So you said it depends on the 07:24:19
machine but you have no idea of any machines 07:24:21
that allow you to just put it in and say, 07:24:23
"Perform chromatography on this," and it 07:24:26
picks the column? 07:24:28
A. I can't recall at this point. 07:24:29
Q. So as far as your training, you 07:24:31
talked about reading in a book and sitting 07:24:40
down with a piece of paper and doing some 07:24:43
calculations. So the types of calculations 07:24:45
that you would have to do, explain those to 07:24:46
me. Or the types of calculations that you 07:24:49
were trained to do in order to perform 07:24:51
chromatography on an automated liquid 07:24:54
chromatography instrument. 07:24:56

Q. And tell me what goes into choosing the column based on the application. 07:32:48 07:32:49 07:32:51

A. You have to look at what things you would like to separate and what affinities they might have and then decide which column to choose. 07:32:53 07:32:56 07:32:59 07:33:04

Q. So for someone as experienced as you, I take it that would just take a few minutes; is that right? 07:33:08 07:33:10 07:33:13

A. The -- well, the choice of the column is an important choice, and I wouldn't characteristic how long it would take. 07:33:15 07:33:18 07:33:20 07:33:23

Q. What do you mean by you wouldn't characterize how long it would take? You have a lot of experience in this field. So given all that experience, I assume you would just be able to pick out a column within a few minutes; right? 07:33:23 07:33:26 07:33:28 07:33:29 07:33:31 07:33:33

A. I wouldn't want to characterize the amount of time it would take me to choose a liquid chromatography column because it varies by the application, it varies by the problem. 07:33:34 07:33:35 07:33:37 07:33:40 07:33:42

Q. Well, give me the range of times it's taken you to select a column. 07:33:44 07:33:46

A. I can't really give a range of times. I guess I could say between -- you know -- in the simplest situation in which you are repeating an analysis that you've done before, the column might already be in the machine, and so that might be zero time. 07:33:50 07:33:52 07:33:55 07:33:58 07:34:00 07:34:02

But on an upper end, I can't really bound that. 07:34:07 07:34:09

Q. Well, why not? I mean, you've -- you say that you have experience in chromatography. I'm assuming there are times when you've done chroma- -- a chromatography experiment that you've never done before. So how long did it take to select a column? 07:34:11 07:34:13 07:34:15 07:34:17 07:34:19 07:34:21 07:34:23

A. Yeah, so there are certainly times when we've done separations that we haven't done before, and those are the times that typically take more. You're stepping away from what you -- processes that you've -- separations that you've performed before. So those typically take longer, but I can't really quantify how long those might 07:34:29 07:34:31 07:34:34 07:34:35 07:34:38 07:34:42 07:34:44 07:34:46

have taken. 07:34:49

Q. Why can't you quantify it? I mean, you were involved, weren't you? 07:34:50 07:34:51

A. Yes, I was involved. But these are -- we're describing now a body of work, and some of it was done a long time ago. So, you know, memory fades. Some of it was done more recently and, you know, they're diverse amounts of time. 07:34:54 07:34:55 07:35:01 07:35:04 07:35:07 07:35:11

Each project has different aspects to it, different separations that you might do, you know, in the course of that project. 07:35:13 07:35:15 07:35:17 07:35:20

So, anyhow, a lot of factors, you know, factor into the choice of the column. 07:35:21 07:35:24 07:35:25

Q. When you say "a lot of factors," explain some of the factors. 07:35:26 07:35:28

A. Well, you need to choose a liquid chromatography column appropriately so that the material that you would like to separate has some contrast with the background of all the other materials that are in that sample. 07:35:30 07:35:33 07:35:36 07:35:40 07:35:44 07:35:47

Q. Are you done? 07:35:51

A. Yes. 07:35:51

Q. Well, so let's take the ones that you've done recently. Describe some of those ones that you've done recently and how hose factors factored in and what kind of time frame we're talking about. 07:35:53 07:35:54 07:35:57 07:35:59 07:36:02

A. Yeah, so recently we've used this FPLC, fast protein liquid chromatography, to collect certain proteins, and we use those proteins to coat a nano bead. The proteins that we're collecting are various, and the backgrounds are also assorted. And so the calculation time is -- you know, it varies, and I can't really quantify that. 07:36:07 07:36:10 07:36:15 07:36:21 07:36:28 07:36:32 07:36:36 07:36:41 07:36:44

Q. Well, you say "it varies." I mean, were you doing any of the calculations? 07:36:46 07:36:47 07:36:49

A. I was overseeing the -- the student who was doing the calculations. 07:36:49 07:36:51

Q. So given that you were overseeing, are we talking about, like, a lunchtime amount of time to do the calculations? A day? A week? What are we talking here? 07:36:53 07:36:56 07:36:58 07:37:00 07:37:03

A. So the way that university professors work is, you know, we study, we -- we advise graduate students and post docs about how to perform their research. And we leave the -- a lot of the research and actual production of knowledge up to the students. The students -- you know, we discuss problems with them and then they go away and they perform calculations. They perform experiments. They -- you know, they think about things. They come back and talk to us.

So how long a calc- -- first of all, I probably don't know how long a student spent on a calculation. But second of all, it's -- we're always working with trainees. These students are always -- we're training them from scratch. And so they might take a longer time to do a calculation in the beginning, and they might take a shorter time to do a calculation toward the end of their research.

Q. So what you're saying, then, is you really don't have a feel for what a reasonable amount of time to do a

calculation to figure out a column is. Fair?

A. I don't believe that was the question that you asked.

Q. Well, do you have an idea of what a reasonable amount of time to do a calculation to determine the column, for example, that you just talked about now, on separating various proteins, you don't really have any idea whether your student that you say you're supervising is spending a reasonable or an unreasonable amount of time doing the calculations; correct?

A. Could you -- could you start that again from the beginning?

Q. Right.

So you just testified about supervising a student who is doing calculations on selecting columns that are being used right now. And would it be fair to say that you do not have an idea of what a reasonable amount of time and what an unreasonable amount of time is to do those calculations?

MR. MILLER: Objection,

foundation.

A. So we're talking about a particular student. And like I said, you know, it's my job to teach these students to do these calculations.

When I send them away to do their research and their calculations, I'm not sure how long they're spending on those calculations. If they come back to me and it's clear that they've been pulling their hair out or they haven't finished, you know, they haven't been able to do these calculations, well, then it's clear that they need some more instruction.

Q. So that wasn't the question.

The question was, do you have an idea of what would be a reasonable amount of time for your student to do the calculations and what would be an unreasonable amount of time?

A. It would depend on -- that depends on the student.

Q. So the student that you have in mind right now, what's that student's name?

A. Hui Ma.

Q. Okay.

For Hui Ma. And is that a master's level student? A PhD-level student? A postdoc? What is it?

A. Quay is a PhD student.

Q. What is a reasonable amount of time and what's an unreasonable amount of time for Hui Ma to perform the calculations you think he's performing now for the chromatography experiments that are occurring under your supervision?

A. To a great extent I don't care how long it takes him to do the calculations. I care that he does the calculations correctly and I care that he understands the process so that he has an insight into the -- you know, the separation that he's trying to perform.

Q. All right.

Well, let me ask you this. Would it affect one way or another, whether he's using an automated liquid chromatography system, the amount of time he spends calculating which column to use?

A. He is using a liquid

will take. It's not -- it's not all you need. It's -- it's a starting point.

Q. So one of the things we talked about is calculations that go into selection of a column, which you need to do whether your system is automated or not -- even when you -- when you have an automated liquid chromatography system for any new separation that you haven't done before, you've got to do calculations on which column you're selecting. Fair?

A. That's correct.

Q. What about -- there are certain chemicals in addition to the sample that you've got to put onto the column as well to get the material -- your sample to get it off the column; correct?

A. There are -- I mean, I guess there's -- first of all, the field of liquid chromatography is really broad, and the range of processes that are performed with liquid chromatography are really broad. But they typically will involve some kind of a carrier fluid that has to be introduced to the column in addition to your sample.

Q. Do you -- in an automated liquid chromatography system when you're performing a separation, a chromatography separation that you haven't done before, do you have to do calculations to identify the carrier fluid?

A. There are -- yes, there are calculations that are required to determine the carrier fluid.

What I mean is -- so when you're doing calculations, there are several kinds of calculations that you might do. For instance, there are calculations that lead to a numerical answer, like the flow rate and consumption of volume calculation. And then there are calculations that you do in another way, which is let's say I use this carrier fluid. Then I do a calculation for how long a separation would take. Let's say I use that carrier fluid. How long would a separation take? Or would it even be possible?

So it's not -- there aren't a finite -- or an infinite number of calculations. There are, you know, let's

say a smaller -- there's a smaller universe of carrier fluid choices.

Q. So when you're -- when you are doing calculations for the carrier fluid, what goes into the selection of what the carrier fluid is going to be?

A. It depends on the separation that you would like to do.

Q. So let's take the one that you say is being done by Mr. Wa -- Ma, excuse me, your graduate student. What goes into the calculations for the carrier fluid that has to be selected for his experiments?

A. Once you've -- so we have to calculate -- we have to determine how close we are to the -- I guess -- so we have to determine the concentration of the sample in the carrier fluid.

Q. Is that it?

A. No, but I can't give you an exhaustive list.

Q. Well, I actually would like an exhaustive list. So let's go through it.

Tell me -- tell me the calculations that you would have to do with

respect to the carrier fluid in the separations that are being performed under your supervision now.

A. I can't give you an exhaustive list at this point.

Q. Well, tell me what you can give me.

A. Sorry, what was the calculation that we were talking about?

Q. The calculations that go into -- that are related to the carrier fluid.

The carrier fluid is going to be responsible for, in one regard, for getting the material off the column; correct?

A. The carrier fluid certainly carries the fluid -- the sample through the column.

Q. What's responsible for knocking the sample off the column at different --

A. It depends -- sorry.

Q. Go ahead.

A. Well, so typically after a separation is performed, then you will flush the column and remove all of the -- let's say all of the remaining material from the

do based on whatever you read or had previously done. 08:22:21 08:22:25
Q. What system was that? 08:22:27
A. I don't recall. I don't know the model name. It probably doesn't exist anymore. 08:22:29 08:22:30 08:22:32
Q. Do you remember the manufacturer? 08:22:33 08:22:35
A. It no, I don't. 08:22:35
Q. Did you -- so in graduate school what were you using that system for? 08:22:37 08:22:41
A. That was -- I was just trained on that system. 08:22:45 08:22:47
Q. So you didn't actually perform any real work that resulted in any kind of publication on that system? 08:22:47 08:22:49 08:22:51
A. So I think it's -- when you're a graduate student, you're trained in a lot of different things, and ideally those topics that you're trained in are focused towards your research area but not all of them end up being in your research area. So liquid chromatography was not something that I needed to do to complete my research. 08:22:54 08:22:59 08:23:02 08:23:06 08:23:09 08:23:11 08:23:13 08:23:15
Q. So when you say you were trained 08:23:19

in it in graduate school, was this a lab? Like, was this course work or was this actually in your advisor's lab he told you, "I need you to learn to do liquid chromatography"? 08:23:22 08:23:24 08:23:27 08:23:31 08:23:33
A. Not -- so it was not a course. And the machine was in a colleague's lab. And so -- and I was trained by a student in that colleague's lab. 08:23:35 08:23:38 08:23:42 08:23:46
Q. For no particular purpose? You didn't have any -- any actual experiments in mind for your graduate dissertation or master's thesis where you were going to need to use liquid chromatography. You just did it because you thought, hey, it might be a good idea to learn this? 08:23:51 08:23:53 08:23:56 08:24:00 08:24:02 08:24:05 08:24:07
A. Graduate school is a time when you learn lots of things. I also took many laser classes that I didn't use, you know, let's say, immediately. I subsequently did use those classes. 08:24:11 08:24:12 08:24:15 08:24:19 08:24:22
But I guess I would say my project, my master's and PhD research, was oriented toward a biomedical device which separates plasma from whole blood. And one 08:24:24 08:24:29 08:24:32 08:24:36

of the potential technologies that we were looking at using in that, in the scope of my -- either my master's or PhD work was liquid chromatography. 08:24:40 08:24:44 08:24:47 08:24:50
We subsequently ultimately did not use it. But -- but, you know, it's like building a house. You have to have the tools on-site in order to build the house. You don't want to have to run down to Builders Square every ten minutes and get a new tool. 08:24:52 08:24:54 08:24:56 08:24:58 08:25:00 08:25:02 08:25:05
Q. Yeah, I'm quite familiar with that. You know, when I was in the lab I also worked with blood. 08:25:07 08:25:08 08:25:10
So aside from using a centrifuge to separate the plasma from, say, red cells, what was your -- what was your research actually on? Because obviously the most common way to separate those is with a centrifuge. 08:25:11 08:25:16 08:25:21 08:25:23 08:25:25 08:25:28
A. Yeah, the -- so the centrifuge approach is typically how cellular components are separated from blood, let's say, after the fact. So if you donate a unit of whole blood, they'll spin down the 08:25:29 08:25:31 08:25:34 08:25:37 08:25:41

cells and then collect the plasma. It depends on what the -- what the goal is. But if the goal is to collect plasma or cellular components, you're right. A centrifuge is oftentimes used. 08:25:46 08:25:49 08:25:51 08:25:53 08:25:55
But I don't know if you've been to donate blood recently, but most of the major blood collection services have a machine that will collect your plasma and return the cellular component to the patient. And the reason obviously is that you can donate plasma twice a week and you can only donate whole blood, I think it's every six weeks. So they have these plasma centers all over the place, you know, where they'll pay people to donate plasma. That's how some people make ends meet. 08:25:57 08:25:58 08:26:04 08:26:08 08:26:13 08:26:17 08:26:19 08:26:21 08:26:26 08:26:29 08:26:30 08:26:33
Q. So one of the things you talked about early on this morning was that you have experience in automated fluid handling systems. Right? 08:26:36 08:26:38 08:26:40 08:26:44
A. I did say that. 08:26:46
Q. How does experience in an automated fluid handling system provide you the experience to act as an expert on an 08:26:47 08:26:49 08:26:54

automated liquid chromatography system? 08:26:58
A. I guess many operations that are 08:27:05
formed in liquid chromatography would be 08:27:08
characterized as automated liquid handling 08:27:12
operations. 08:27:16
Q. Which ones? 08:27:18
A. Pumping, valving, detecting, 08:27:23
that sort of thing. 08:27:27
Q. What kinds of components do you 08:27:30
need to deliver automated controlled fluid 08:27:32
flow to a column, to a chromatography 08:27:39
column? What components? 08:27:42
A. So I'm -- is this question 08:27:47
you're asking me just about in order to 08:27:50
deliver the fluid to the column? 08:27:55
Q. That is correct. 08:27:58
And I'm just going to note that 08:27:59
I do think you're kind of like fading in and 08:28:01
out a little bit right now, your voice. 08:28:03
A. Yeah. Okay. Sorry. 08:28:07
Q. Go ahead. 08:28:07
A. Yeah. 08:28:12
So the -- just to make sure 08:28:12
we're both on the same page. So I'm 08:28:15
delivering the fluid to the column. 08:28:17

determinable, user-determinable flow rate. 08:29:13
And potentially I would need to measure that 08:29:20
flow rate to ascertain that I've actually, 08:29:22
you know, gotten the flow rate that I 08:29:24
programmed. 08:29:26
Potentially I might need some 08:29:27
valving. But pretty much that's it in this 08:29:29
hypothetical. 08:29:34
Q. So when you say "potentially" 08:29:35
you might need something to make sure that 08:29:36
your flow rate is correct, what do you mean 08:29:39
by that? 08:29:44
A. So there are many different 08:29:47
kinds of pumps in -- you know, in the world 08:29:49
of pumps, and there are pumps that will 08:29:52
deliver a -- when I -- called metering pumps 08:29:57
that will deliver a known flow rate. So I 08:30:02
punch in "Give me so many milliliters per 08:30:04
hour," and I get that many milliliters per 08:30:07
hour. 08:30:09
There are other pumps that won't 08:30:09
give me have that degree of certainty. And 08:30:11
so if I was using one of those other types 08:30:13
of pumps, then I would have to -- to measure 08:30:15
the flow rate -- 08:30:18

Q. That is correct. 08:28:20
A. Okay. So at a minimum I would 08:28:22
need a pump and -- well, okay. At a minimum 08:28:25
I would need a pump. 08:28:30
Q. Anything else? 08:28:32
A. So just to deliver a controlled 08:28:36
flow to a column -- 08:28:38
Q. Well, let's say to a column and 08:28:39
through the column. 08:28:41
A. And do I care what I'm 08:28:45
collecting at the output of this column? 08:28:46
Q. No, just deliver automated 08:28:48
controlled flow through a column. 08:28:51
A. Okay. 08:28:53
So now the question is deliver 08:28:54
an automated controlled flow through the 08:28:56
column -- 08:28:59
Q. That's it. 08:29:00
A. -- and out of the column, and I 08:29:00
don't care what happens after it comes out 08:29:02
of the column? 08:29:03
Q. Correct. 08:29:03
A. Okay. 08:29:05
So I would need a pump that can 08:29:06
deliver a flow rate that's settable, a 08:29:09

Q. Okay. 08:30:21
A. -- to verify it. 08:30:21
Q. So if I had a pump where I could 08:30:21
set it to X mils per minute, that's what 08:30:23
you're talking about are as far as a pump 08:30:27
that's delivering a set amount? 08:30:31
A. Yes. 08:30:37
I mean -- okay. So -- and it 08:30:38
has to -- we have to know about that pump, 08:30:41
that that number is reliable. 08:30:44
Q. So, for example, if I -- you 08:30:47
know, like one of the ones I use frequently 08:30:50
was a syringe pump. Syringe pump has a -- 08:30:52
has gradations on it. It'll -- you know, 08:30:56
you can see it's like -- I mean, let's take 08:30:58
a small syringe. 10 mils. Actually, that's 08:31:00
pretty small. But let's say 50 mils. And 08:31:05
you have every 10 mils there is a line. You 08:31:10
could easily just see whether the piston or 08:31:15
the plunger is moving 10 mils over a set 08:31:18
period of time. I mean, I could watch it 08:31:25
with a watch and see it go from 50 to 40 in 08:31:27
X number of seconds and then watch it go 08:31:30
from 40 to 30 in X number of seconds. 40 to 08:31:31
30. And if it's consistent, then I know, 08:31:36

MR. MILLER: Objection, form. 12:46:04
A. I guess this calls for me to 12:46:06
answer a question about the mental state of 12:46:12
the person you're talking about. The why 12:46:16
question I can't answer that. 12:46:18
Q. So you do understand that to say 12:46:20
something is not obvious, you actually have 12:46:23
to do that as an expert? You have to come 12:46:26
up with a reason why, using normal 12:46:28
creativity, that step would not be obvious 12:46:31
to a hypothetical person? 12:46:34
MR. MILLER: Objection, form. 12:46:36
I'm not even sure that's a question, 12:46:43
but form. 12:46:44
A. Could you repeat the question? 12:46:45
Q. Do you understand that as an 12:46:45
expert saying that something is not obvious, 12:46:47
you have to answer the question why a 12:46:49
hypothetical person would not, given all the 12:46:51
knowledge which exists in the world as they 12:46:55
sit there, why they wouldn't think of going 12:46:57
from what already existed in the world to 12:46:59
the new thing, what impediments there would 12:47:01
have been, something that would have steered 12:47:05
them away from that or talked them away from 12:47:06

for certain -- for certain automated liquid 12:48:16
processes. 12:48:23
Q. And there is nothing about 12:48:24
chromatography like if you create a module 12:48:26
that's going to do something for 12:48:29
chromatography and you put it into a housing 12:48:31
that someone of ordinary skill in the art 12:48:33
would know, "Hey, if you do that, like, the 12:48:35
instrument is going to blow up. You can't 12:48:37
do it. Like, you need some radioactive 12:48:39
component, and if you put it into a module 12:48:41
and put that module into a housing, it's 12:48:43
going to melt the metal and it's going to 12:48:45
contaminate everything and you're going to 12:48:48
have an explosion." There's nothing like 12:48:49
that right? 12:48:52
MR. MILLER: Objection, form. 12:48:53
A. I haven't seen anything along 12:48:56
the lines of what you described. 12:48:57
Q. So then why wouldn't -- again, 12:48:59
why wouldn't this hypothetical person with 12:49:01
normal creativity who has experience in 12:49:03
designing automated fluid handling systems, 12:49:06
has experience with automated liquid 12:49:09
chromatography systems, why would they, 12:49:12

that? I mean, there's nothing in the 2040 12:47:09
that says anywhere in the manual or anywhere 12:47:11
about it, "Hey, this thing can only be used 12:47:13
for this -- the applications that are loaded 12:47:16
on the machine," is there? 12:47:19
A. In the manual for the 2040, 12:47:26
there -- you're asking if there is anything 12:47:28
in the manual for the 2040 that says you 12:47:30
can't do automated liquid chromatography? 12:47:32
Q. It says you can only use this 12:47:34
system for the -- for the applications which 12:47:36
are already preloaded on this machine. 12:47:39
A. I don't believe so. But I would 12:47:45
have to look at the manual again to confirm 12:47:47
that. 12:47:49
Q. So there's no teaching away -- 12:47:52
there's no teaching from anything that 12:47:53
you've seen that says the 2040 can only be 12:47:55
used for X, Y and Z applications and no 12:47:58
other by a person of ordinary skill in the 12:48:02
art? You've never seen anything like that; 12:48:04
correct? 12:48:06
MR. MILLER: Objection, form. 12:48:07
A. I don't believe I've seen 12:48:12
anything that said the 2040 can't be used 12:48:13

knowing about the 2040, knowing everything 12:49:14
else in the world, all the prior art, why 12:49:16
would they think that this design of the 12:49:18
2040 could not be used to design an 12:49:21
automated liquid chromatography system in 12:49:24
2005? 12:49:28
MR. MILLER: Objection, form. 12:49:30
A. I don't know. 12:49:33
Q. You don't have any -- when you 12:49:46
say "I don't know," you can't give any 12:49:48
reason why they would not think that this 12:49:49
could be applied to designing an automated 12:49:51
liquid chromatography system, this design of 12:49:55
the 2040? 12:49:57
A. Could you repeat the question? 12:49:59
Q. When you say "I don't know," you 12:50:03
can come up with no reason why this person 12:50:05
of ordinary skill in the art, knowing 12:50:07
everything in the prior art, knowing about 12:50:09
the 2040, why that person would think that 12:50:11
that design that's used in the 2040 of an 12:50:14
automated fluid handling system could not be 12:50:19
used for an automated fluid handling system 12:50:22
that performs the application of 12:50:24
chromatography; correct? 12:50:28

A. That is what I said, yes. 12:50:30
Q. Let's take a look at your 12:50:34
rebuttal report which -- I've got to find 12:50:41
it. 12:51:06
[Pause.] 12:51:10
Q. While we're waiting, at any of 12:51:24
the breaks they have you spoken to anyone? 12:51:26
A. Yes, I have. 12:51:29
Q. Who did you speak to at the 12:51:29
breaks? 12:51:31
A. I spoke to Mr. Miller. 12:51:31
Q. At each one of the breaks? 12:51:35
A. Yes, I believe so. 12:51:37
Q. Did you talk about any of the 12:51:39
testimony that you've given? 12:51:40
A. No. 12:51:40
Q. What did you talk about? 12:51:43
A. He asked about my mental state. 12:51:47
You know, inquired as to how I was doing, 12:51:51
you know, how I was feeling, that sort of 12:51:55
thing. 12:51:56
Q. Didn't discuss of any the 12:51:58
testimony that you've given or any of the 12:52:00
test- -- well, let me start with that. 12:52:03
Didn't discuss of any the testimony that 12:52:05

you've given? 12:52:07
A. I mean, to the extent that my -- 12:52:08
how I'm feeling, how I'm doing is related to 12:52:12
the testimony. You know, I -- there was 12:52:15
nothing substantive. It was -- it was 12:52:19
entirely, you know, like, "How are you 12:52:22
doing? How is everything going?" That sort 12:52:26
of thing. 12:52:28
Q. Did you talk about any questions 12:52:29
that may be coming up and how to answer 12:52:31
those? 12:52:33
A. No, we did not. 12:52:34
Q. All right. 12:52:34
Let take a look at Exhibit 12:52:41
Number 103. 12:52:43
[Deposition Exhibit 103 marked 12:52:43
for identification.] 12:52:43
A. Okay. 12:52:58
Q. Do you recognize -- do you see 12:52:58
103 now? 12:53:00
A. I see it, yes. 12:53:01
Q. And you recognize this as a 12:53:02
report that you participated in preparing? 12:53:03
A. Actually, I should -- well, I 12:53:06
knew it was the rebuttal report. So I was 12:53:09

looking at the version on my computer. But 12:53:10
I should look at the version that you 12:53:12
posted. So just give me a second. 12:53:14
Q. I mean, quite honestly I don't 12:53:17
really care which one you look at. 12:53:18
A. Okay. 12:53:20
Q. I'm going to refer to paragraph 12:53:20
numbers, but I am referring to Exhibit 12:53:22
Number 103, which is the official one that 12:53:25
will be in the record. 12:53:26
A. Okay. Yes. 12:53:28
Q. So if you go to Exhibit Number 12:53:30
264, which is on page 364 of the rebuttal 12:53:33
report. 12:53:37
A. Okay. 12:53:41
Q. Are you there? 12:53:44
A. I'm getting there. Let's see. 12:53:45
264? 12:53:54
Q. Paragraph number 264, which 12:53:54
appears on the numbered page 364. 12:53:57
A. Okay. Yes, I have it. 12:54:05
Q. So is this a paragraph that you 12:54:06
wrote? 12:54:09
A. Yes. 12:54:09
Q. In paragraph 264 you say: 12:54:25

"The System" -- and I assume 12:54:28
you're referring to the 2040 system; right? 12:54:30
A. Wait a second. Wait. 264? 12:54:35
Q. Paragraph number 264. 12:54:41
A. So I have "The 2040 System...." 12:54:44
so maybe -- 12:54:48
Q. That's the first -- those are 12:54:49
the first three words. If you go down one, 12:54:50
two, three, four, five -- five lines on the 12:54:56
right-hand side. 12:54:57
A. Yes. 12:54:57
Q. Okay. 12:54:58
It says "The System...." 12:54:58
Do you see that? 12:55:01
A. Yes, yes, I see that. 12:55:01
Q. "The System...." 12:55:02
I assume you're describing the 12:55:03
2040 system; correct? 12:55:04
A. Yes. 12:55:04
Q. "...is described for industrial 12:55:06
use and specifically designed to handle a 12:55:09
wide range of applications." 12:55:12
Do you see that? 12:55:15
A. Yes, I do. 12:55:16
Q. What do you mean by "a wide 12:55:17

MR. BILSKER: Sean, I'm looking for the '470 patent, Bergstrom. Where is it? 15:30:03 15:30:18 15:30:23

MR. DAMON: It is GEHC_001775-Bergstrom. 15:30:32 15:30:39

MR. BILSKER: Got it. Sorry. 15:30:41

[Deposition Exhibit 106 marked for identification.] 15:30:41 15:31:14

BY MR. BILSKER: 15:31:14

Q. Sir, do you remember that in Bergstrom the fluid line was 5 and the electrical line was 12 in base plate 1; right? Do you remember that? 15:31:14 15:31:15 15:31:17 15:31:20

A. I -- I haven't been keeping that in my memory. 15:31:22 15:31:24

Q. Let's take a look at -- so you have Exhibit 106? 15:31:25 15:31:28

A. Let's see. There we go. Okay. I've got to refresh this. 15:31:28 15:31:39

Okay. I see Exhibit 106 has appeared. I'm going to download it. 15:31:48 15:31:50

All right. Wait. Downloads. Okay. 15:32:00 15:32:02

I got it. 15:32:03

Q. So if you look at Exhibit 106 15:32:04

and you look at figure number 1 -- do you see figure number 1? 15:32:07 15:32:11

A. That's on the first page; correct? 15:32:12 15:32:17

Q. Well, I don't know if it's on the first page or the second page. It's not very hard to find. It says figure 1. 15:32:17 15:32:18 15:32:20

A. Oh, yeah. Okay. There it is. 15:32:22

Q. In figure 1 you see something labeled 12; right? 15:32:25 15:32:27

A. Figure number 1. 15:32:27

Yes, I do. 15:32:32

Q. And it looks like a series of little dots; right? 15:32:33 15:32:35

A. I see that, yes. 15:32:36

Q. And you have something labeled 5, and 5 goes to something that says 1, 2, 3. 15:32:37 15:32:39 15:32:39

Do you see that? 15:32:43

A. I do. 15:32:44

Q. Those things are separated; correct? 15:32:45 15:32:47

MR. MILLER: Objection, form. 15:32:50

A. They are distinct entities. 15:32:52

Q. Right. So they're separated 15:32:56

just like the LEDs and the display in the Bio-Rad device and the fluidic components in the Bio-Rad device; right? 15:32:57 15:33:04 15:33:07

A. I wouldn't characterize them as separated just like the LEDs and the fluid components. 15:33:09 15:33:11 15:33:15

Q. Well, they are separated; right? 15:33:16

A. Yes. They are not the same thing. So -- 15:33:20 15:33:21

Q. Yeah. 15:33:22

A. -- they do that occupy the same space. So they are separated. 15:33:23 15:33:24

Q. Well, the inventor said at page red 31 of the prior exhibit -- 15:33:25 15:33:27

So if we go back to the prior exhibit. 15:33:37 15:33:39

A. Okay. 15:33:39

Q. Which now I don't remember what it was. It's 104. So you go to red 31 of 104. 15:33:50 15:33:52 15:33:54

A. Okay. Let me see. Red 31 of 104. 15:33:56 15:33:59

Okay. 15:34:05

Q. It says about in the middle of the page -- well, starting at the top [as 15:34:05 15:34:07

read]: 15:34:07

"However, the fluidics and non fluidics of the modules are not separated in Bergstrom, as in presently claimed invention. The module (4) shown in Figure 4 has no electrical parts described, and so it cannot have the fluidic and non-fluidic sections as in presently claimed invention." 15:34:15 15:34:16 15:34:19 15:34:24 15:34:28 15:34:32 15:34:35 15:34:40

Well, we know that's not true because we just looked at electrical line 12; right? 15:34:40 15:34:42 15:34:44

"More relevant, Applicants believe, is the module 10 which has both fluid and electrical paths but they occupy adjacent paths." 15:34:45 15:34:47 15:34:51 15:34:55

"Adjacent." That means near each other. Right? 15:34:57 15:34:58

A. Well, adjacent? 15:35:04

Yeah. Yes. More or less. 15:35:09

Q. So the LED lights in the accused device, those are adjacent to fluid paths in the accused device; correct? 15:35:11 15:35:13 15:35:16

A. The LED lights are adjacent to the fluid -- yeah, they're relatively close. 15:35:18 15:35:23

Q. And then it goes on to say [as read]: 15:35:33
"The modules of Bergstrom do not separate their fluidic and electrical parts (where they have them)" blah blah blah. 15:35:34
"The detector module 10 of Figure 10 illustrates that fluid and electrical parts are adjacent and not on either side of a panel." 15:35:41
Wow! That seems problematic for you. They're saying in a detector you've got electrical and fluidic parts that are on the same sides of a panel and they're saying that verboten. 15:35:53
"The detector module of Figure 10 illustrates that fluid and electrical parts are adjacent, and not on either side of a panel. There is no suggestion in Bergstrom that fluidic and non fluidic parts are separated as in presently claimed invention. In Bergstrom, the opposite is taught - that the fluidic and non fluidic parts are together." 15:36:06
Wow! Doesn't that shake your confidence that a detector module with an 15:36:35

electronic component right next to a fluidic component can actually be the invention? 15:36:39
A. I'm not sure of the question there. 15:36:42
Q. Well, this says that a detector, where you have an electronic component right next to a fluidic component, just like all detectors do, is not the invention. 15:36:44
MR. MILLER: Objection. 15:36:49
Q. And you just said, "No problem." 15:36:50
A. Right. 15:36:54
Q. "I'll just call it a fluidic component, not an electrical component" when we were talking about the pH valve and pH electrode; right? 15:36:57
MR. MILLER: Objection, form. 15:37:03
A. The separation in the Bergstrom patent is -- is different. You know, it's a completely different thing. 15:37:07
MR. MILLER: Mr. Bilsker, it's been seven hours. So if you can wrap it up, please, that would be great. 15:37:10
MR. BILSKER: Sean, where is the Notice of Allowability? 15:37:12
MR. DAMON: The first two. So 15:37:16

the first one is the rejection. The second one is the notice of allow. It says "Notice" in it, "718 File History." 15:37:17
MR. BILSKER: Got it. 15:37:29
[Deposition Exhibit 107 marked for identification.] 15:37:29
BY MR. BILSKER: 15:37:29
Q. Dr. Wereley, you have in front of you, or you should have in a second, what's been marked as Exhibit Number 107. 15:37:29
Now, you remember discussing the Hess reference in response to what Dr. Gale wrote; correct? 15:37:29
MR. MILLER: Are you changing subjects? Because it's been seven hours. So I'll cut you -- 15:37:29
MR. BILSKER: We're still on the file history with the prior art. I have about five more minutes. 15:37:29
MR. MILLER: Are you going to cut us the same courtesy next week? 15:37:29
MR. BILSKER: Yes. 15:37:29
BY MR. BILSKER: 15:37:29
Q. So you remember discussing the 15:37:29

Hess reference in relation to something that Dr. Gale wrote where he said this thing -- the way the inventors distinguish the Hess reference, the one that you have the electrical cord coming outside of a box -- even though the box had electronics in it, there was an electrical cord coming outside of the box, and they said, "Ah, you've got an electrical cord coming out of the box. Therefore, your electronics section -- your electronic components are not internal to the housing." 15:37:29
You remember that? 15:37:29
A. I remember discussing the Hess reference. I need to refresh my memory on that. 15:37:29
Q. And do you remember saying, "Oh, all that discussion about electronics and Hess was irrelevant because the way they were disting- -- the way the inventors distinguished Hess was they were just saying that Hess didn't have a housing." 15:37:29
Do you remember that? 15:37:29
A. I don't recall that. I need to refresh my memory on that. 15:37:29

PAUL J. FREDERICKSON, CSR
CA CSR 13164
Expiration date January 31, 2021

****
WITNESS SIGNATURE
****

I, STEVEN WERELEY, PhD, do hereby declare under penalty of perjury that I have read the foregoing transcript of my deposition; that I have made such corrections as noted herein, in ink, initialed by me, or attached hereto; that my testimony as contained herein, as corrected, is true and correct.

EXECUTED this_____day of_____, 2020, at_____(City), _____(State).

_____
STEVEN WERELEY, PhD

EXHIBIT L

From: Sean Damon
Sent: Thursday, October 29, 2020 7:42 AM
To: Sebba, Michael <Michael.Sebba@arnoldporter.com>
Cc: asilverstein@potteranderson.com; bpalapura@potteranderson.com; dmoore@potteranderson.com; Brge Team <BrgeTeam@quinnemanuel.com>; jshaw@shawkeller.com; SKGEHealthcare@shawkeller.com; GE - BioRad <GE-BioRad@arnoldporter.com>; Felipe Corredor <felipecorredor@quinnemanuel.com>
Subject: Re: Cytiva v. Bio-Rad, No. 18-1899 - 2040 System Inspection

Michael—

We have read your email numerous times and cannot find an answer to the simple question we asked. You have continually been requesting "program" files for the 2040 machine and insisting that unless you receive those you will move to exclude Dr. Gales report that shows the 2040 performs chromatography. We have now told you on at least a dozen occasions, that no "programming" exists as that term is normally understood – writing code. Parameters were simply selected off the machine's menu-driven interface as it exists in its normal course. Even those values are not relevant to anything as the values existed on the machine. Nonetheless, we gave you screenshots of what you called the "program files" but you still complained.

Our question was simple. What in particular are you saying you do not have from the machine in terms of "programs" you have been requesting that we have the capability to provide. You were not able to answer that question or how this mysterious information is relevant to anything. That silence speaks for itself.

We have fully complied with our obligations under the Federal Rules. Information that was relied on was provided.

Best regards,

Sean Damon
Attorney at Law,
Quinn Emanuel Urquhart & Sullivan, LLP

1300 I Street, NW, Suite 900
Washington, D.C. 20005
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From: "Sebba, Michael"
Date: Tuesday, October 27, 2020 at 3:59 PM
To: Sean Damon
Cc: "asilverstein@potteranderson.com" , "bpalapura@potteranderson.com" , "dmoore@potteranderson.com" , Brge Team , "jshaw@shawkeller.com" ,

"SKGEHealthcare@shawkeller.com" , GE - BioRad , Felipe Corredor
Subject: RE: Cytiva v. Bio-Rad, No. 18-1899 - 2040 System Inspection

[EXTERNAL EMAIL]

Sean,

We are surprised that you would ask why our requests are relevant. Bio-Rad is attempting to invalidate Cytiva's patents using the experiments referenced in Exhibit 4 to Dr. Gale's Opening Report (the "2040 Experiments"). Clearly any information related to the 2040 Experiments is highly relevant. Furthermore, your suggestion that we propose what documents are in Bio-Rad's or Dr. Gale's possession is improper. Such a proposal is a blatant attempt at burden shifting. Once again, our understanding from our correspondence is that neither Bio-Rad, its counsel, nor Dr. Gale possesses any further discoverable information that can be provided to Cytiva relating to the 2040 System, including any documents, videos, or electronic files. If this is not the case, please let us know ASAP and be prepared to discuss this during our meet and confer conference.

Furthermore, in Dr. Gale's response to the subpoena, he stated that all documents "that were located after a reasonable search" were produced. Please let us know what this reasonable search entailed. In addition, Dr. Gale objected to RFPs 4 and 5 because they "seek[] information that is protected by the attorney-client privilege, work-product doctrine, and/or any other privilege, immunity, or protection afforded by law." However, in a prior meet and confer, QE stated that the only documents withheld based on privilege or work product were drafts of Dr. Gale's report. Please let us know if there were other documents responsive to RFPs 4 and 5 withheld based on privilege or work product and provide a log of any such documents.

Finally, please let us know your availability to meet and confer on these issues on Wednesday or Thursday.

Regards,

Mike

Michael J. Sebba
Associate

Arnold & Porter
250 West 55th Street | New York, New York 10019-9710
T: +1 212.836.7529
Michael.Sebba@arnoldporter.com | www.arnoldporter.com

From: Sean Damon
Sent: Friday, October 23, 2020 3:54 PM

To: Sebba, Michael
Cc: asilverstein@potteranderson.com; zzz.External.bpalapura@potteranderson.com ; zzz.External.dmoore@potteranderson.com ; Brge Team ; zzz.External.jshaw@shawkeller.com ; SKGEHealthcare@shawkeller.com; GE - BioRad ; Felipe Corredor
Subject: Re: Cytiva v. Bio-Rad, No. 18-1899 - 2040 System Inspection

External E-mail

Mike—

You have the 2040 System Manual, the student's lab book, and now pictures of the program that Dr. Gale relied upon despite failing to take them yourself during the inspection. Please tell us what else you think is accessible beyond the materials we provided and explain how it is relevant.

We have, now on numerous occasions, explained the system is not "programmed" in the manner it appears you believe.

Regards,

Sean Damon
Attorney at Law,
Quinn Emanuel Urquhart & Sullivan, LLP

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From: "Sebba, Michael" <Michael.Sebba@arnoldporter.com>
Date: Friday, October 23, 2020 at 5:12 PM
To: Sean Damon <seandamon@quinnemanuel.com>
Cc: "asilverstein@potteranderson.com" <asilverstein@potteranderson.com>, "bpalapura@potteranderson.com" <bpalapura@potteranderson.com>, "dmoore@potteranderson.com" <dmoore@potteranderson.com>, Brge Team <BrgeTeam@quinnemanuel.com>, "jshaw@shawkeller.com" <jshaw@shawkeller.com>, "SKGEHealthcare@shawkeller.com" <SKGEHealthcare@shawkeller.com>, GE - BioRad <GE-BioRad@arnoldporter.com>, Felipe Corredor <felipecorredor@quinnemanuel.com>
Subject: RE: Cytiva v. Bio-Rad, No. 18-1899 - 2040 System Inspection

[EXTERNAL EMAIL]

Sean,

We write regarding Bio-Rad's production of images of the chromtest2 file.

As we have explained before, the information available on the system is insufficient. Instead we requested the specific programming that was devised and/or the specific inputs into the 2040 System used to perform the experiments referenced in Exhibit 4, as well as the other items referenced in my prior emails. Sending eight photographs of what Dr. Wereley already reviewed on the system at the inspection does not remedy this.

Our understanding is that Bio-Rad's position is that there is no more information that can be provided, including documents, videos, or the actual electronic files relating to the 2040 System. If our understanding is incorrect, we are available to meet and confer regarding this issue early next week. If there is no additional information that can be provided regarding the experiments referenced in Exhibit 4, we will no longer pursue this discovery dispute and reserve all our rights, including the right to file an appropriate motion with respect to Dr. Gale's reliance on the experiments referenced in Exhibit 4.

Regards,

Mike

Michael J. Sebba
Associate

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Michael.Sebba@arnoldporter.com | www.arnoldporter.com

From: Sean Damon <seandamon@quinnemanuel.com>
Sent: Monday, October 19, 2020 8:11 PM
To: Sebba, Michael <Michael.Sebba@arnoldporter.com>
Cc: asilverstein@potteranderson.com; zzz.External.bpalapura@potteranderson.com <bpalapura@potteranderson.com>; zzz.External.dmoore@potteranderson.com <dmoore@potteranderson.com>; Brge Team <BrgeTeam@quinnemanuel.com>; zzz.External.jshaw@shawkeller.com <jshaw@shawkeller.com>; SKGEHealthcare@shawkeller.com; GE - BioRad <GE-BioRad@arnoldporter.com>; Felipe Corredor <felipecorredor@quinnemanuel.com>
Subject: Cytiva v. Bio-Rad, No. 18-1899 - 2040 System Inspection

External E-mail

Michael—

See the attached correspondence.

Download: Associated files with correspondence.

Best regards,

Sean Damon
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_____
For more information about Arnold & Porter, click here:
http://www.arnoldporter.com

EXHIBIT M

BRUCE KENT GALE

Professor and Chair of Mechanical Engineering, University of Utah
Director, State of Utah Center of Excellence for Biomedical Microfluidics
1495 E 100 S Room 1550 MEK, Salt Lake City, UT 84112
Phone (801) 585-5944 Fax (801) 585-9826
E-mail: bruce.gale@utah.edu http://www.mems.utah.edu

Education

September, 1995 to August, 1999	**PH.D. IN BIOENGINEERING** University of Utah Major Subjects: Microelectromechanical Systems (BioMEMS), Analytical Biosensors, VLSI Fabrication, Microfluidics, Cell and Tissue Engineering Dissertation Chair: A. Bruno Frazier	SEPTEMBER 1999 Salt Lake City, UT
September, 1990 to June, 1991 and January, 1994 to August, 1995	**B.S. IN MECHANICAL ENGINEERING** Brigham Young University Major Subjects: Control Systems, Robotics, Compliant Mechanisms	AUGUST 1995 Provo, UT

Academic Appointments

July 2018 to present	**Chair,** Mechanical Engineering, University of Utah
July 2013 to present	**Professor**, Mechanical Engineering, University of Utah.
July 2013 - present	**Adjunct Professor,** Bioengineering; Electrical and Computer Engineering; Materials Science and Engineering, all at the University of Utah
July 2007 to June 2013	**Associate Professor**, Mechanical Engineering, University of Utah.
July 2007 – June 2013	**Adjunct Associate Professor,** Bioengineering; Electrical and Computer Engineering; Materials Science and Engineering, all at the University of Utah
July 2004 to present	**Director,** Utah State Center of Excellence for Biomedical Microfluidics. Supervise, direct, and perform research on biomedical microdevices important to the economy of the state of Utah.
February 2002 – June 2007	**Adjunct Assistant Professor,** Bioengineering; Electrical and Computer Engineering; Materials Science and Engineering, all at the University of Utah
Dec 2001 to June 2007	**Assistant Professor**, Mechanical Engineering, University of Utah. Teach classes in Mechanical Engineering, advise students, and perform research involving MEMS devices and their applications to in microfluidics and sensing.
August, 1999 to Dec 2001	**Assistant Professor**, Biomedical Engineering, Louisiana Tech University. Teach classes in Biomedical Engineering, advise students, and perform research involving MEMS devices and their applications to biology and medicine.
Sept 1995 to August, 1999	**Graduate Research Assistant**, Micro Instrumentation Research Laboratory and Center for Biopolymers at Interfaces, University of Utah.

Industrial Appointments

December, 2004 to present	**Founder and Director of Research**, Carterra (formerly Wasatch Microfluidics), Salt Lake City, Utah.
January, 2010 to 2017	**Chief Science Officer**, Guanine, Inc., Salt Lake City, Utah.
February, 2013 to present	**Founder, Chairman and Chief Science Officer,** Espira, Inc., Salt Lake City, Utah.
January 2016 to present	**Founder and Vice President of Engineering,** Nanonc, Inc., Salt Lake City, Utah.
January 2016 to present	**Founder and Vice President of Engineering,** Microsurgical Innovations, Inc., Salt Lake City, Utah.
May 2018 to present	**Founder and Vice President of Engineering,** WFluidx, Inc., Salt Lake City, Utah.

Teaching and Graduate Student Training

Fall 2012, 2013, 2014, 2016, 2017	Instructor, ME EN 2450 Numerical Methods for Sustainable Engin. Design (3 h)
Spring 2011-2012, 2015	Instructor, ME EN 4010 Senior Design II (3 h)
Fall 2009-2011, Spring 2013, -15, -17	Instructor, ME EN 5/6960 and ECE 5/6962 and Bioen 5900 Microfluidic Chip Design and Fabrication (3 h)
Spring 2006/-08/-18/-20	Instructor, ME EN 7960 and Bioen 6900 Microfluidic Design and Simulation (3 h)
Fall 2002-2007, 2019	Instructor, ME EN 2400 &2410 Dynamics, University of Utah (4 h)
Spring 2002,-03,-05,-07, -13	Instructor, ME EN 5960 & 6960, ECE 5221 and 6221, BIOEN 6421 Introduction to Micromachining, University of Utah (3 h)
Fall 2001	Instructor, MSE 501 Microsystems Principles, Louisiana Tech (3 h) (67 students)
Winter 2000-2001	Instructor, BIEN 550C Biomedical Microsystems, Louisiana Tech (3 h)
Spring 2000 and 2001	Instructor, BIEN 420 Biomaterials and Biomechanics, Louisiana Tech (3 h)
Winter 1999-2000	Instructor, BIEN 515 Biosensors and Their Applications, Louisiana Tech (3 h)
Fall 1999 and 2000	Instructor, BIEN 500 Physiology for Engineers, Louisiana Tech, (4 h)
Fall 1998	Co-Instructor, BE 6900 & EE 6960: Micromachined Instrumentation Systems University of Utah. (3 h)

Graduate Students Graduated

University of Utah

No.	Name	Thesis Topic	Degree	Dept	Defense Date
1	Nithin Narayanan	Microscale SPLITT Fractionation	MS	ME	Aug 2004
2	Aju Badardeen	Oxygen Sensing Using Electrostatic Layer by Layer Assembly	MS	ME	December, 2004
3	David Chang-yen	Design of Microscale Fluidic Sensing Arrays	PhD	ME	April 2005
4	Ameya Kantak	Microscale Cyclical Electrical Field Flow Fractionation	PhD	ME	July 2005
5	Rajesh Gopalakrishnan	Nanoassembled Glucose Sensing	MS	ECE	Nov 2005
6	Siddharth Chakravarthy	Polymerized Liposome Analysis with FFF	MS	ME	Dec 2005
7	Ryan Sincic	DNA Extraction from Cancer Cells	MS	Bioen	May 2006
8	Casey Pehrson	Microneedle Arrays	MS	ME	May 2006
9	Josh Eckman	Microfluidic Spotter Design	MS	ME	Dec 2006
10	John Maxwell	Integrated Electronics and Pneumatics	MS	ME	Aug 2007

11	Tammy Ho	A Novel Paraffin-Based Microactuator	MS	Bioen	Dec 2007
12	Sriram Natarajan	High density biomolecule spotting systems	PhD	ChemE	April 2008
13	Niel Crews	Ultra High Speed DNA Analysis	PhD	ME	May 2008
14	Himanshu Sant	Microscale Field Flow Fractionation	PhD	Bioen	June 2008
15	Mark Eddings	Integrated biomolecule spotting systems	PhD	Bioen	Aug 2008
16	Jungkyu Kim	Integrated High Density DNA Extraction and Analysis	PhD	Bioen	Sept 2008
17	Clint Holtey	Microvalves Integrated into Printed Circuit Boards	MS	ME	Dec. 2008
18	Merugu Srinivas	Modeling of Cyclical Electrical Field Flow Fractionation	PhD	ECE	April 2009
19	Rahul Sonkul	Hybrid PDMS/PMMA Microfluidic Systems	MS	ME	May 2009
20	Rajesh Surapaneni	DNA Extraction	MS	ME	Dec 2009
21	Rohit Sharma	Real time DNA extraction measurement	MS	ME	Dec 2009
22	Venu Arremsetty	Microscale Flow SPLITT System	MS	ME	May 2010
23	Austin Welborn	Modeling of microfluidic eye implants	MS	ME	Aug 2010
24	Scott Sundberg	High density arrays for Homogenous RT-PCR	PhD	Bioen	Dec 2010
25	Doug Anjewierden	Electrostatic Integrated Valves for Microfluidics	MS	ME	May 2011
26	Keng-Min Lin	A Novel Drug Delivery Device for the Eye	MS	ME	May 2011
27	Erik Liddiard	Microfluidic Worm Sorting	MS	Bioen	Aug 2011
28	Victoria Ragsdale	Heat Transfer Analysis of Polymers for Flow PCR	MS	ME	Dec 2011
29	Cody Gehrke	Vascular Coupling Device	MS	ME	May 2012
30	Onur Tasci	Nanoparticle Characterization using Electrical FFF	PhD	Bioen	May 2013
31	BJ Minson	Polycarbonate Microfluidic DNA Analysis Systems	MS	ME	May 2013
32	Nathan Gooch (co)	Intraocular Drug Delivery Device	PhD	Bioen	May 2013
33	Michael Johnson	Microfluidic Systems for Rapid Biological Assays	PhD	ME	Aug 2013
34	Raheel Samuel	Microfluidic Systems for Neurotechnology	PhD	ME	April 2014
35	Keng Min Lin	Miniature Drug Delivery Devices	PhD	ME	April 2014
36	Harikrishnan Jayamohan	Nanoscale Bacteria Sensing Systems	PhD	ME	May 2015
37	Huizhong Li	A Vascular Coupling Device	PhD	ME	May 2015
38	Scott Ho	Manufacture of Nerve Regeneration Devices	MS	ME	June 2015
39	Russ Reid	Contact Lens Biofuel Cell	PhD	ME	Dec 2015
40	Jiyoung Son	Microfluidic Cell Separations	PhD	ECE	May 2017
41	Pratima Labroo	Nerve Regeneration Devices	PhD	ME	May 2017
42	Ryan Brewster	PLGA Vessel Anastomosis	MS	ME	May 2017
43	Kevin Petersen	Exosome Separations	PhD	ME	May 2018
44	Arlen Chung	Zebrafish Genotyping Chip Optimization	MS	ME	May 2018
45	Valentin Romanov	Synthesis of Lipid Vesicles using Rapid Prototyping	PhD	ME	Dec 2018
46	Joshua Burton	Novel Nerve Regeneration Devices	MS	BME	Dec 2018
47	Farhad Shiri	Separation of Virus Like Particles	PhD	ME	May 2020
48	Marzieh Chaharlang	Modeling of Sperm Transport in Inertial Microfluidics	PhD	Physics	May 2020
49	John Nelson	Simulation of a Vascular Coupling Device	MS	Bioen	May 2020
50	Haidong Feng	Inertial Microfluidics for Cell Processing	PhD	ME	Aug 2020
51	Alex Jafek	Sperm Separations using Inertial Microfluidics	PhD	ME	Aug 2020

Louisiana Tech University

No.	Name	Thesis Topic	Degree	Dept	Defense Date
1	Mengyan Li	Microstructures for Tissue Engineering	MS	BME	April 2002
2	Avinash Saldanha	Viral Separations using a Micro SPLITT	MS	ECE	April 2002
3	Krishnan Padmanabhan	Impedance Spectroscopy Detection of Nanoparticles	MS	ECE	April 2002
4	Himanshu Sant	Scaling In EFFF	MS	BME	April 2002
5	David Chang-yen	Oxygen Sensitive Self Assembled Films	MS	BME	August 2002
6	Merugu Srinivas	Cyclical Electrical Field Flow Fractionation	MS	ECE	August 2002

Mahidol University, Bangkok, Thailand (Co-Advisor)

No.	Name	Thesis Topic	Degree	Dept	Defense Date

1	Wilaiwan Somchue	Nanoparticle Characterization using ElFFF	PhD	Chemistry	April 2012
2	Mathuros Ornthai	Improved CyElFFF for Nanoparticle Analysis	PhD	Chemistry	January 2016

Graduate Students Currently Supervised

#	Name	Thesis Topic	Degree	Dept	Expected Grad. Date
1	Greg Liddiard	Integrated Microfluidic DNA Analysis	PhD	ECE	May 2022
2	Jesus Arellano	Continuous Flow Cells Integrated with Microscopy	PhD	Bioen	May 2020
3	Brett Davis	Nerve Regerneration Devices	PhD	Bioen	May 2020
4	Ugochukwu Nze	Cell Separation Devices	PnD	ME	May 2020
5	Chris Lambert	High throughput Zebrafish Genotyping	PhD	ME	Dec 2021
6	Matt Nelson	Organ on a Chip Systems	PhD	Bioen	May 2021
7	Mike Beeman	Electrochemical Pathogren Detection	PhD	ME	May 2020
8	Brady Goenner	96 Channel Valve Card	PhD	ME	May 2022
9	Utpal Saha	Microfluidic Sperm Analysis Devices	PhD	ECE	May 2022
10	Tawsif Mahmood	Electrochemical Detection of Pathogens	PhD	ME	May 2022
11	Dhruv Patel	Pathogen Analysis using Cavitation	PhD	ME	May 2022
12	Nusrat Tazin	Zebrafish Instrumentation	PhD	ECE	May 2023
13	Susan Wojtalewicz	Nerve Regeneration Wrap	MS	ME	May 2022

Post Doctoral Training Supervised

#	Name	Dates
1	David Chang-yen	April 2005- April 2007
2	Himanshu Sant	July 2008 – June 2013
3	Jungkyu Kim	September 2008 – August 2009
4	John Elsnab	September 2008 – December 2009
5	Merugu Srinivas	October 2009 – September 2010
6	Scott Sundberg	December 2010 – May 2011
7	Raheel Samuel	May 2014 – present
8	Harikrishnan Jayamohan	July 2015 – March 2016
9	Mohammad Rajesh Khan	December 2017 – present

Undergraduate Student Research Projects Advised

#	Name	Dates
1	Adam Miles	2004-2006
2	Andrew Christensen	2004-2005
3	Jenny Greer	2005-2007
4	John Brady	2005
5	Ahmed Bradshaw	2005-2006
6	Joel Marsh	2005-2006
7	Chris Morrow	2006-2007
8	Dieter Bevans	2006-2007
9	Phillip Brough	2007-2008
10	Avdo Cutic	2008-2009
11	Darren Johnson	2009-2010
12	Johnny Lop Ng	2009-2010
13	Cory Shorr	2010-2011
14	Chao Gao	2010-2011
15	Faris Ali	2010-2012
16	Rinchen	2011-2012
17	Scott Ho	2011- 2013
18	Chris Lambert	2011- 2014
19	Rebecca Klaus	2012-2013
20	John Nelson	2013- 2016

#	Name	Dates
21	Ryan Brewster	2014- 2016
22	Naveen Rathi	2014-2018
23	Megan Roach	2014-2016
24	Jordan Davis	2014-present
25	Sean Jones	2014-2015
26	Rainey Cornaby	2014-2016
27	Taylor Howell	2014-2015
28	Matthew Givens	2014
29	Brody King	2015-present
30	Derek Dunford	2015-2016
31	Susan Wojtalewicz	2015-2018
32	Travis White	2015-2017
33	Kristina Royzman	2015-2016
34	Blair Gerratt	2014-2015
35	Edgar Vasquez	2015-2016
36	Nicholas Miller	2014-2016
37	Nika Belova	2015-2016
38	Daniel Zhu	2016-2018
39	Carlos Vinatea	2016
40	Connor Morgan	2016-2017

#	Name	Dates
41	Sierra Erickson	2016-present
42	Sean Harbertson	2016-present
43	Hayden Brady	2016-present
44	Polly Creveling	2017
45	Jesse Griffin	2017-2018
46	Kade Lansford	2017-present

#	Name	Dates
47	Gareth Graves	2018-present
48	Hyonoo Joo	2018-2019
49	Chidi Ahanonu	2018-present
50	Elaine Wong	2020-present
51	Madison Hanson	2020-present

Senior Design Projects Advised

#	Project	Dates	Students
1	Microneedles	2003-2004	Matthew Bown, Mark Eddings, Marc Leatherman, Casey Pehrson Scott Sundberg, Scot Waye, Mike Wyatt
2	DNA Extraction System	2004-2005	Lisa Bailey, Robert Bell, Jensen Dobbs, Brendan Perkins
3	Neurotap Mechanical Inserter	2004-2005	Daniel Cooley, Matt Mikkelsen, James Harris Richard Kiser, Ted Holt, Ryan Davis
4	Desalinization Device	2005-2006	Bryon Conner, Greg Hansen, Brad Tippetts, Richard Allen, Matt Goodro, Adam Pyper
5	Microfluidic Spotter	2005-2006	Jacob Browning, Louis Monaco, Todd Andelin, Christopher Weaver
6	DNA Melting Analysis	2007-2008	Christian Sellers, Steven Rabe, Seth Plazier, Jenny Greer, Dan Torgerson, Chad Meeks
7	DNA Haplotyping Disk	2008-2009	Avdo Cutic, Stuart Burton, Nellie Huynh
8	Arterial Coupler	2009-2010	Brian Stauffer, Lam Nguyen, Cory Shorr, Cody Gehrke
9	Mechanical Leech	2012-2013	Scott Ho, Jessica Kuhlman, Ladan Jiracek, Vic Walker, Andy Thompson
10	Rheumatoid Arthritis Sensor	2014-2015	Jaron Peck, Sarah Bentley, Rachel Ware, Parker Vance
11	96 Channel Pump	2015-2016	Bryan Luke, Rodolfo Garcia, Tanner Hatch, Brian Butler
12	Rising Toilet Seat	2015-2016	Cody Mitchell, Khoa Dinh, Brandon Wilstead, Jose Garcia
13	Low Cost Insulin Pump	2016-2017	
14	Stem Cell Separations	2016-2017	Megan Roach, Joelle Hardy, Brianna Potter, Nelson Nieto, Travis Gowen
15	Sperm Cell Processing	2018	Trevor Teerlink, Cameron Hendricks, Jaron Ortega, Daniel Folsom, Mitch Shepherd
16	96 Channel Peristaltic Pump	2018	Connor Wade, Brian Lee, Evan Smail, Joseph Blash
17	Zebrafish Embryo Dispenser	2018-2019	Brett Reeder, Hanna Nizam, Daniel Lee
18	Drum Screen for Municipal Wastewater Treatment	2019	Adnan Khan, Kyle Mays, Jeremy Nguyen, Alik Nielsen, Thomas Pembroke
19	Andrology Clinic in a Box	2019	Daniel Mochizuki, Travis Simpson, Natalia Dominguez, Gabriel Milla

High School Student Research Projects Advised

#	Name	Dates
1	Dani Roush	Summer 2008
2	Bryan Cerda	Spring 2010
3	Matthew Bohman	Summer 2010
4	Kristen Johnsen	Summer 2011
5	Parker Awerkamp	Summer 2011
6	Naveen Rathi	Summer 2013 & 2014
7	Jacob Alder	Spring 2013
8	Lia Gale	Summer 2014
9	Sam Bonkowsky	May 2017-present

Consulting

November 2018 – present	Qiagen, Patent Infringement Cases
July 2018 – October 2019	Confluent Surgical, Patent Infringement Cases
October 2014 - present	BioRad, Inc. Patent Infringement Cases
Sept 2010 – June 2011	Alcon Pharmaceuticals, Patent Infringement Case
August 2010 – June 2011	Roche Diagnostics, Patent Infringement Case
July 2007 – December 2011	Early Warning, Inc.
September 2005 – 2009	Member scientific advisory board for Center for BioModular Multi-Scale Systems (Louisiana State University); Paid position
December 2004 – present	Chief Technology Officer, Carterra (formerly Wasatch Microfluidics LLC)
October, 2004 – July 2005	Roche Diagnostics, Patent Infringement Case

Honors and Awards

April 2020	University of Utah Distinguished Research Award
April 2019	Honoree in the Entrepreneur Category at the 2019 Celebrate U event
April 2018	Honoree in the Entrepreneur Category at the 2018 Celebrate U event
August 2017	Researcher of the Year for 2016, Mechanical Engineering Department
September 2016	TVC Star Award
August 2014	Researcher of the Year for 2013, Mechanical Engineering Department
May 2014	Distinguished Mentor Award, University of Utah
August 2013	Researcher of the Year for 2012, Mechanical Engineering Department
Fall 2004, 2010, 2011	Top 15% Instructor Commendation, College of Engineering
April, 2004	Nominated for Student Choice Teaching Award
September 2001	Louisiana Tech College of Engineering Outstanding Researcher Award
1996-1999	NSF Graduate Research Fellowship
March 1996	Awarded Whitaker Foundation Graduate Research Fellowship
1995-1996	Whitaker Foundation Biobased Engineering Internship
August 1995	Mechanical Engineering Outstanding Student at Graduation Award

Proposal and Research Activities

Currently Funded Projects

Rapid processing of zebrafish embryos for mutant generation, wFluidx/NIH, PI, $219,000, Aug 2020 – Jan 2021.

Standard Microfluidic Chip, Medic.life, PI, $19,000, April 2020-July 2020.

Ion Separations using Electrical Field Flow Fractionation, Metrohm, PI, $79,000, April 2020 – Dec 2020

A Biodegradable Vascular Coupling Device for End-to-End Anastomosis, NIH/Microsurgical Innovations, co-PI, $1,650,000, August 2016 – July 2020

Sperm sample preparation for point of care applications, Nanonc/NIH, co-PI, $1,225,000, April 2018 – September 2020.

An Integrated Biohazard Analyzer for Multiplexed Food and Water Pathogens, Espira/DOD, co-PI, $1,050,000, April 2017-August 2019.

University of Utah Manufacturing Extension Partnership Center, NIST, co-PI, $12,000,000, October 2016-September 2021.

Completed Projects

Ion Current Rectification (ICR) Biosensing Biomedical Technologies, EBS (NIH), PI, $117,000, September 2017- August 2019.

Microfluidic Sensor Enhancement, Qorvo, PI, $44,000, May 2018 – December 2018.

Microfluidic Valve Card Array, Carterra, PI, $48,000, January 2018 – December 2018.

Nanopore Tools for RNA Analysis, EBS (NIH), PI, $50,000, September 2017- June 2018.

Nanotoxicology Assays Using a Microfluidic Array, UURF, PI, $17,500, July 1, 2017-June 30, 2018.

A Vascular Coupling Device, Utah TCIP, co-PI, $150,000, April 2016-March 2018.

Continuous Separations of Oncosomes from Exosomes, Espira/NIH, co-PI, $300,000, October 2016- Sept 2017.

Microfluidic Devices for Early (less than 48 hpf), non-destructive Zebrafish Genotyping, co-PI, $225,000, September 2016 – August 2017.

HT Label-Free Screening and Kinetic Analysis of Small Molecules and Biologics, NIH, co-PI, $1,300,000, May 2014 – April 2017

Enhancing Peripheral Nerve Regeneration with a Novel Drug-Delivering Nerve Conduit, DOD, co-PI, $750,000, October 2013 – September 2016.

Rapid sperm separations using inertial microfluidics, NSF STTR, co-PI, $225,000, January 2016-December 2016.

Passive microfluidic flow cells, Becton Dickinson/Boston University, PI, $25,000, March 2015-October 2016.

Nanopore Enabled Exonuclease Sequencing, NIH/Electronic Bioscience, subcontract PI, $15,000, October 2016-April 2017.

Tacrolimus Release in a Nerve Regeneration Device, UURF Engine, $25,000, June 2015 – May 2016.

Continuous Separation of Melanoma Exosomes Using Field-Flow Fractionation, NIH, PI, $560,000, August, 2013 – July, 2016.

Multiplexed bacteria, virus, and protozoa detection, DOD/Espira, co-PI, $100,000, October 2015 –September 2016.

Microfluidic GWAS, Mayo Clinic, $79,000, September 2015 – August 2016.

Nanoparticle Characterization, Pfizer, PI, $50,000, October 2015 – September 2016.

High Sensitivity Bacteria Detection, TCIP State of Utah, co-PI, $50,000, Jan 2015 – June 2016.

High Sensitivity Virus Detection, Espira Inc, PI, $30,000, May 2014 – April 2016.

Multiplexed Ovarian Cancer Microfluidic Tissue Microarray, NIH, co-PI, $225,000, June 2014 – December 2015.

Microfluidics Shared Equipment, UURF RIF, PI, $62,600, January 2015-December 2015.

IGERT: Nanobiosensors, Nanomaterials, and Microfluidics, NSF, co-PI, $3,000,000, August 2009 – July 2015.

Raman Laser Tweezers, UURF RIF, co-PI, $65,000, January 2015-December 2015.

Keck Center for Scaling Engineering Education: Transforming Undergraduate Micro/Nano Education through Scaling Engineering, Keck Foundation, co-PI, $200,000, December 2012 – May 2015.

Arterial Coupling Device, GOED, TCIP, co-PI, $120,000, May 2011 – May 2015.

A Drug Delivery Conduit for Nerve Regeneration, DOD, co-PI, $186,000, September, 2013 – May, 2015.

Arterial Coupling Device, UURF, Engine, co-PI, $30,000, January 2014 – May 2014.

Rapid bacteria detection from wastewater effluent, UURF, Engine, co-PI, $33,000, November 2013 – September 2014.

SBIR: 96 Channel Continuous Flow Print head and Integrated Flow Cell System, NIH/NIMH, PI, $1,056,000, August 1, 2008 – September 30, 2014.

SBIR: Submerged Printing of Lipid and Membrane Protein Arrays, NIH/NIGMS, PI, $350,000, September 1, 2012 – August 31, 2014.

SPLITT-based detection and monitoring of engineered nanomaterials in aquatic systems, NSF, co-PI, $418,000, September 2010 – August 2013.

K-Wire Drug Delivery Device, UofU TCP, co-PI, $35,000, January 2012-December 2013.

Nerve Regeneration Drug Delivery Device, UofU Seed Grant, co-PI, $31,000, July 2012 – June 2013

Near-Time Effluent Quality Sensor Technology for Organics and Bacteria for Shipboard Wastewater Treatment Systems, DOD SBIR, co-PI, $80,000, February, 2013 – August, 2013.

A Power-Free Complete Blood Count, I-Calc, PI, $36,000, August 15, 2012 – December 31, 2012.

Arterial Coupling Device, UofU TCP, co-PI, $70,000, January 2011 – December 2012.

Microfluidics for multiple engineering disciplines. NSF, PI, $60,000, December 1, 2008 – November 30, 2012.

Microneedle Arrays for Drug Delivery, PI, Hong Kong University, $15,700, July – October 2011.

Early Cancer Detection Platform: Sample In, Answer Out, U of U TCP/USTAR, PI, $120,000, January 2010 – December 2011.

Combined Flow Cytometry, Confocal Microscopy, and Highly Parallel Microfluidic Flow Cells, RIF, PI, $120,000, February 2010 – December 2010.

In Vivo Pressure Measurement and Drug Delivery for the Eye, UofU Seed, PI, $31,000, January 2011 – December 2011.

Rapid Detection of Foot and Mouth Disease, Indian Immunologicals, PI, $54,500, February 2010 – August 2011.

A High-throughput Flow-cell for Biosensor Platforms, NSF, PI, $600,000, July 1, 2008 – August 31, 2011.

Impact, Detection, and Tracking of Nanoparticles in Agriculture: A Focus on Crops and Rhizosphere Microbes, USDA, co-PI, $442,086, January 2009 – December 2011. USDA-CSREES grant 2009-35603-05037

Spinning Disk Digital Microfluidics, UofU TCP, co-PI, $70,000, July 1, 2008-June 30, 2010

SBIR: Parallel Microfluidic System for High Throughput Label Free Cytokine Analysis, NIH/NIAID, PI, $200,000, July 1, 2008 – December 30, 2009

SBIR: Highly Parallel AIDS Assays Using A Microfluidic Flow Cell Array Integrated with SPR, NIH, PI, $100,000, April 2009 – March 2010.

SPLITT-based detection and monitoring of engineered nanomaterials in aquatic systems, U of U Seed, co-PI, $22,000, July 2009 – June 2010.

Instruments for detection of bacteria in environmental water, Early Warning Inc, PI, $775,000, August 1, 2007-November 30, 2009

Generic Platform for DNA Sample Preparation, Univ of Utah TCP, PI, $70,000, Aug 1, 2007 – July 31, 2009.

Integrated Pneumatic and Electrical Systems, Idaho Technology, PI, $103,557, February 1, 2006 – September 30, 2008.

DNA Melting Analysis in High Speed Microfluidic Chips, Canon US Life Sciences, co-PI, $135,000, April 1, 2007 – March 31, 2008.

Small Molecule Removal Using SPLITT Techniques, Hallandia Ventures, PI, $20,000, May 1, 2007 – October 31, 2007

Microfluidics Based Braille Cell, Tactile Response, PI, $20,000, November 1, 2006- October 31, 2007.

State of Utah Center of Excellence for Biomedical Microfluidics, GOED, PI, $455,000, July 1, 2004 – June 30, 2007.

Synergy: Development of a Technology for Personalized Medicine, U of U Synergy Program, PI, $100,000, July 1, 2006- June 30, 2007

Microneedle Development, ZARS, PI, $25,000, June 22, 2006 – November 21, 2006

Volume Manufacturing of 48 Spot CFM Devices, Wasatch Microfluidics, PI, $49,335, October 1, 2006 – March 31, 2007.

University TA, U of U, co-PI, $12,000, August 2006 – May 2007.

Development of an International Engineering Experience Course, U of U, $4,000, PI, August 2006 – May 2007.

A Graduate Training Program in Micro Thermal Fluids, NSF-IGERT, co-PI, $3,500,000, August 1, 2000 – July 30, 2006.

Osmotic Pumps, Foxboro, co-PI, $37,000, January, 2005 – August, 2005.

High Resolution Laser Micromachining System, U of U RIF, PI, $35,000, July 1, 2004 – June 30, 2005.

Pressure Compensation in Micropumps, Ceramatec, co-PI, $5,000, June 1, 2004 – May 31, 2005.

Viscous Microscale Pump, University of Utah– TCP Program, co-PI, $70,000, July 1, 2003 – June 30, 2005.

Planning Grant for Center of Excellence in Biomedical Microfluidics, State COEP, $5,000, November, 2003 – February, 2004, PI.

University TA, U of U, $11,000, August, 2003 – May, 2004, co-PI.

High Throughput Nanoparticle Separations Using Highly Parallel Electrical SPLITT Technology, University of Utah TTO – TCP Program, PI, $70,000, July 1, 2002 – June 30, 2004.

Microstructures for Directed Smooth Muscle Cell Growth, Louisiana Board of Regents RCS Program, PI, $130,500, July 1, 2001- June 30, 2004.

One-Two Three Go: A Strategic Initiative for Rapid Research Competitiveness in Microsystems Development (Salary and Research Enhancements), Louisiana BoR DEFE Program, co-PI, $910,000, Jun 2000 - May 2005.

Louisiana EPSCoR Research Infrastructure Improvement Award, NSF EPSCoR and Louisiana BoR, $13,500,000 ($2,850,000 under my direction), co-PI (coordinate activities of 12 investigators at seven research institutions and interface with other PIs), June 1, 2001- May 31, 2004.

Microfabricated Electrical Field Flow Fractionation Systems for Detection of Biowarfare Agents, United Engineering Foundation, PI, $25,000, January 2001 – December 2001.

Microstructures for Directed Cardiac Muscle Cell Growth, Rockefeller Brothers Foundation, PI, $25,000, January 1, 2001-December 31, 2001.

Biosensor Array, Los Alamos National Lab, PI, $16,053, May 1, 2001- July 15, 2001.

Optical Devices using X-ray Lithography, 3M Corporation, $70,000, co-PI, Sep 2000 - Mar 2001

Scholarly Activities and Publications

Submitted Journal Articles

1. Wilaiwan Somchue, Atitaya Siripinyanond, and Bruce K. Gale, "Cyclical Electrical Field-Flow Fractionation for Metal Nanoparticles Characterization," *Electrophoresis*, submitted.

Published Journal Articles

1. Brett Davis, Sierra Erickson, Susan Wojtalewicz, Andrew Simpson, Cameron Metcalf, Himanshu Sant, Jill Shea, Bruce Gale, Jay Agarwal, "Entrapping bupivacaine-loaded emulsions in a crosslinked-hydrogel

increases anesthetic effect and duration in a rat sciatic nerve block model," *International Journal of Pharmaceutics*, accepted. https://doi.org/10.1016/j.ijpharm.2020.119703

2. Alex Jafek, Haidong Feng, Hayden Brady, Kevin Petersen, Marzieh Charharlang, Kenneth Aston, Bruce Gale, Timothy Jenkins, Raheel Samuel, "An Automated Instrument for Intrauterine Insemination Sperm Preparation," *Scientific Reports*, accepted.
3. Alex Jafek, Haidong Feng, Dallin Broberg, Bruce Gale, Raheel Samuel, Kenneth Aston, Timothy Jenkins, "Optimization of Dean-flow microfluidic chip for sperm preparation for intrauterine insemination," *Microfluidics and Nanofluidics*, accepted.
4. Farhad Shiri, Bruce K. Gale, Himanshu Sant, Gina Bardi, Joshua Hood, Kevin Petersen, "Characterization of Human Glioblastoma versus Normal Plasma-derived Extracellular Vesicles Pre-isolated by Differential Centrifugation using Cyclical Electrical Field-flow Fractionation, *Anal. Chem*., accepted.
5. Cathy L. Mangum, Darshan P. Patel, Alexander R. Jafek, Raheel Samuel, Tim G. Jenkins, Kenneth I. Aston, Bruce K. Gale, and James M. Hotaling, "Towards a better testicular sperm extraction: novel sperm sorting technologies for non-motile sperm extracted by microdissection TESE," *Transl Androl Urol*. Vol. 9(Suppl 2), pp. S206–S214, 2020. doi: 10.21037/tau.2019.08.36
6. Pratima Labroo, Scott Ho, Himanshu Sant, Jill E Shea, Jayant Agarwal, Bruce Gale, "Modelling diffusion based drug release inside a nerve conduit-In vitro and In vivo validation study," *Drug Delivery and Translational Research*, published pre print. doi: 10.1007/s13346-020-00755-y
7. Haidong Feng, Matthew Hockin, Shuhua Zhang, Mario Cappechi, Bruce K. Gale, Himanshu Sant, "Enhanced Chromosome Extraction from Cells Using A Pinched Flow Microfluidic Device," *Biomed. Microdev*., accepted.
8. Farhad Shiri, Kevin E. Petersen, Valentin Romanov, Qin Zou, and Bruce K. Gale, "Characterization and Differential Retention of Q beta bacteriophage Virus-like Particles using Cyclical Electrical Field-Flow Fractionation and Asymmetrical Flow Field-Flow Fractionation," *Anal. Bioanal. Chem*., accepted.
9. Raheel Samuel, Haidong Feng, Alex Jafek, Timothy G. Jenkins, Jiyoung Son, Bruce K. Gale, Douglas Carrell, Jim Hotaling, "Microfluidic system for rapid isolation of sperm from microdissection TESE specimens," *Urology*, Vol. 140, pp. 70-76, 2020. https://doi.org/10.1016/j.urology.2019.12.053
10. Ligeng Shao, Kevin Petersen, Farhad Shiri, Haidong Feng, Bruce Gale, "Characteristics of electrical field flow fractionation with chronoamperometry and electrochemical impedance," *Micro & Nano Letters*, Vol. 15, pp. 13-17, 2020. DOI: 10.1049/mnl.2018.5663
11. Haidong Feng, Jules J. Magda, and Bruce K. Gale, "Viscoelastic second normal stress difference dominated multiple-stream particle focusing in microfluidic channels," *Applied Physics Letters,* Vol. 115, pp. 263702, 2019. DOI: 10.1063/1.5129281.
12. Brett Davis, Jill Shea, Bruce K. Gale, Jay Agarwal, "FK506 delivery at the direct nerve repair site improves nerve regeneration," *Muscle and Nerve*, Vol. 60, pp. 613-620, 2019. DOI: 10.1002/mus.26656
13. Matt Nelson, Nirupama Ramkumar, Bruce K. Gale, "Flexible, transparent, sub-100 μm microfluidic channels with FDM 3D-printed thermoplastic polyurethane," *J. Micromech. Microeng*. Vol. 29, pp. 095010 (8 pp), 2019. https://doi.org/10.1088/1361-6439/ab2f26
14. Valentin Romanov, John McCullough, Bruce K. Gale, Adam Frost, "A tunable microfluidic device enables cargo encapsulation by cell-or organelle-sized lipid vesicles comprising asymmetric lipid bilayers", *Advanced Biosystems*, Vol. 3, pp. 1900010 (9 pages), 2019. DOI: 10.1002/adbi.201900010
15. Ugochukwu C. Nze, Michael G. Beeman, Christopher J. Lambert, Ghadhanfer Salih, Bruce K. Gale, Himanshu J. Sant, "Hydrodynamic cavitation for the rapid separation and electrochemical detection of Cryptosporidium parvum and Escherichia coli O157:H7 in ground beef," *Biosensors and Bioelectronics*, published online April 6, 2019. https://doi.org/10.1016/j.bios.2019.04.002

16. Jiyoung Son, Alexander R. Jafek, Douglas T. Carrell, James M. Hotaling, and Bruce K. Gale, "Sperm like particle (SLP) behavior under curved microfluidic channel and its application to inertial microfluidics principles," *Microfluidics and Nanofluidics*, Vol. 23:4, 2019. https://doi.org/10.1007/s10404-018-2170-1.

17. Jie Zhang, Sudeepa Bhattacharyya, Robert C. Hickner, Alan R. Light, Christopher J. Lambert, Bruce K. Gale, Oliver Fiehn, Sean H. Adams, "Skeletal muscle interstitial fluid metabolomics at rest and associated with an exercise bout: application in rats and humans," *AJP-Endocrinology and Metabolism*, Vol. 316, E43-E53, 2019.

18. Pratima Labroo, David Hilgart, Brett Davis, Himanshu J. Sant, Bruce K. Gale, Jill Shea, Jayant Agarwal, "Drug-delivering nerve conduit improves regeneration in a critical sized gap," *Biotechnology and Bioengineering*, Vol. 116, No. 1, pp. 143-154, 2019. DOI: 10.1002/bit.26837

19. Kevin Petersen, Farhad Shiri, Travis White; Gina Bardi, Himanshu Sant, Bruce Gale, Joshua Hood, "Exosome Isolation: Cyclical Electrical Field Flow Fractionation in Low Ionic Strength Fluids," *Anal. Chem*, Vol. 90, pp. 12783-12790, 2018.

20. Alexander R. Jafek, Chris Lambert, Brady Goenner, Hossein Moghimifam, Ugochukwu Nze, Suraj Kumar, Bruce K. Gale, "A Review of Current Methods in Microfluidic Device Fabrication and Future Commercialization Prospects," *Inventions*, Vol. 3, pp. 60 (25 pages), 2018; doi:10.3390/inventions3030060.

21. Valentin Romanov, Raheel Samuel, Marzieh Chaharlang, Alexander R. Jafek, Adam Frost, and Bruce K. Gale, "FDM 3D Printing of High-Pressure, Heat-Resistant Transparent Microfluidic Devices," *Anal. Chem.,* Vol. 90 (17), pp. 10450-10456, 2018; DOI: 10.1021/acs.analchem.8b02356

22. Brett Davis, Susan Wojtalewicz , Pratima Labroo, Jill Shea, Himanshu Sant, Bruce K. Gale, and Jayant Agarwal, "Controlled release of FK506 from micropatterned PLGA films: Potential for application in peripheral nerve repair," *Neural Regeneration Research*. Vol. 13, 1247-1252, 2018

23. Raheel Samuel, Haidong Feng, Alex Jafek, Dillon Despain, Timothy Jenkins, Bruce Gale, "Microfluidic—based sperm sorting & analysis for treatment of male infertility," *Translational Andrology and Urology*, Vol. 7(Suppl 3): S336–S347, 2018. doi: 10.21037/tau.2018.05.08.

24. Raheel Samuel, Nicholas Miller, Odgerel Badamjav, Timothy Jenkins, James Hotaling, Douglas Carrell, Bruce Gale, "Design and operation of a microfluidic chip for trapping, and off-chip collection of a few human sperm," *J. Micromech. Microeng.*, Vol. 28, pp. 097002, 2018. Doi:10.1088/1361-6439/aac40f.

25. Michael G. Beeman, Ugochukwu C. Nze, Himanshu J. Sant, Hammad Malik, Swomitra Mohanty, Bruce K Gale, Krista Carlson, "Electrochemical Detection of E. coli O157:H7 in Water after Electrocatalytic and Ultraviolet Treatments Using a Polyguanine-Labeled Secondary Bead Sensor," *Sensors,* Vol. 18(5) pp. 1497, 2018.

26. Alexander Jafek, Sean Harbertson, Hayden Brady, Raheel Samuel, Bruce K. Gale, "Instrumentation for xPCR incorporating qPCR and HRMA," *Anal. Chem*., Vol. 90 (12), pp 7190–7196, 2018. DOI: 10.1021/acs.analchem.7b05176

27. Scott Ho, Pratima Labroo, Keng-min Lin, Himanshu Sant, Jill Shea, Bruce K. Gale, Jay Agarwal, "Designing a bioresorbable drug delivery conduit to promote nerve regeneration-a preliminary study," *Journal of Medical and Biological Engineering*, 2018. DOI: 10.1007/s40846-018-0393-y

28. Christopher J. Lambert, Briana C. Freshner, Arlen Chung, Tamara J. Stevenson, D. Miranda Bowles, Raheel Samuel, Bruce K. Gale, Joshua L. Bonkowsky, "An automated system for rapid cellular extraction from live zebrafish embryos and larvae: development and application to genotyping," *PLOS ONE*, published March 15, 2018. DOI: 10.1371/journal.pone.0193180

29. Ching-Wen Li, Jill Shea, Himanshu Sant, Jay Agarwal, Bruce K. Gale, "Optimization of Micropatterned PLGA Films for Enhancing Dorsal Root Ganglion Cell Orientation and Extension," *Neural Regeneration Research*, Vol. 13(1), pp. 105-111, 2018. DOI: 10.4103/1673-5374.224377

30. Ryan Brewster, Bruce K. Gale, Himanshu J. Sant, Ken Monson, Jill Shea, Jay Agarwal, "A Biodegradable Vascular Coupling Device for End-to-End Anastomosis," *Journal of Medical and Biological Engineering*, published on the web December 7, 2017. DOI: /10.1007/s40846-017-0348-8

31. Jiyoung Son, Raheel Samuel, Bruce K. Gale, Douglas T. Carrell, James M. Hotaling, "Separation Of Sperm Cells From Samples Containing High Concentrations Of White Blood Cells Using A Spiral Channel," *Biomicrofluidics*, Vol. 11, pp. 054106, 2017. DOI: /10.1063/1.4994548.

32. Pratima Labroo, Jill Shea, Kyle Edwards, Scott Ho, Brett Davis, Himanshu Sant, Isak Goodwin, Bruce K. Gale, Jay Agarwal, "Novel drug delivering conduit for peripheral nerve regeneration," *Journal of Neural Engineering*, Vol. 14(6), pp. 066011, 2017. doi: 10.1088/1741-2552/aa867d.

33. Jesús Arellano, Taylor Howell, James Gammon, Sungpil Cho, Margit Janat-Amsbury, and Bruce Gale, "Use of a highly parallel Microfluidic Flow Cell Array to determine therapeutic drug dose response curves," *Biomedical Microdevices,* Vol. 25, No. 19, 2017. DOI: 10.1007/s10544-017-0166-3.

34. Huizhong Li, Jill Shea, Himanshu Sant, Bruce K. Gale, Christi Terry, Jay Agarwal, "Vascular Coupling System for End-to-End Anastomosis - An *In Vivo* Pilot Case Report," *Cardiovascular Engineering and Technology,* Vol. 8, No. 1, pp. 91-95, March 1, 2017.

35. Pratima Labroo, Jill E Shea, Himanshu Sant, Bruce K Gale, Jayant Agarwal, "Effect of combining FK506 and neurotrophins on axonal branching and elongation," *Muscle & Nerve*, Vol. 55(4), pp. 570–581, 2017. DOI: 10.1002/mus.25370

36. Vicki Ragsdale, Huizhong Li, Himanshu Sant, Tim A. Ameel, and Bruce K. Gale, "A Disposable Continuous-flow Polymerase Chain Reaction Device-Design, Fabrication and Evaluation" *Biomedical Microdevices*, Vol. 18, No. 4, pp. 1-9, 2016.

37. Pratima Labroo, Scott Ho, Himanshu Sant, Jill Shea, Bruce K. Gale, Jayant Agarwal, "Controlled Delivery of FK506 to Improve Nerve Regeneration," *Shock,* Vol. 46(3 Suppl 1), pp. 154-9, 2016. doi: 10.1097/SHK.0000000000000628

38. Russell C. Reid, Sean R. Jones, David P. Hickey, Shelley D. Minteer, Bruce K. Gale, "Modeling Carbon Nanotube Connectivity and Surface Activity in a Contact Lens Biofuel Cell," *Electrochim. Acta,* Vol. 203, pp. 30-40, 2016.

39. Keng-Min Lin, Jill Shea, Bruce Gale, Himanshu Sant, Patti Larrabee, Jay Agarwal, "Nerve growth factor released from a novel PLGA nerve conduit can improve axon growth," *J Micromech. Microeng.*, Vol. 26 (4), pp. 045016, 2016.

40. Raheel Samuel, Odgerel Badamjav, Kristin E Murphy, Darshan P Patel, Jiyoung Son, Bruce K Gale, Douglas T Carrell, James M Hotaling, "Microfluidics: The Future of Microdissection TESE Sperm Processing?" *Systems Biology in Reproductive Medicine,* Vol. 62(3), pp.161-170, 2016.

41. Deng Yan, Chen Jiao, Zhao Yi, Choy Kwong Wai, Xu Yan, Hu Jun, Himanshu J Sant, Bruce K Gale, and Tang Tao, "Microneedle Array Delivery of siRNA to Skin for Gene Silencing," *Scientific Reports,* Vol. 6, pp. 21422, 2016.

42. Mathuros Ornthai, Atitaya Siripinyanond, and Bruce K. Gale, "Effect of Ionic and Non-Ionic Carriers in Electrical Field-Flow Fractionation, *Anal. Chem.*, Vol. 88 (3), pp 1794–1803, 2016.

43. Harikrishnan Jayamohan, York Smith, Bruce K Gale, Swomitra K Mohanty, Manoranjan Misra, "Photocatalytic Microfluidic Reactors Utilizing Titania Nanotubes on Titanium Mesh for Degradation of Organic and Biological Contaminants," *Journal of Environmental Chemical Engineering,* Vol. 4, No. 1, pp. 657–663, 2016.

44. Mathuros Ornthai, Atitaya Siripinyanond, and Bruce K. Gale, "Biased Cyclical Electrical Field-Flow Fractionation for Separation of Submicron Particles," *Anal. Bioanal. Chem.*, Vol. 408, No. 3, pp. 855-863, 2016. DOI: 10.1007/s00216-015-9173-5

45. Huizhong Li, Jay Agarwal, Brittany Coats, and Bruce K. Gale, *"*Optimization and Evaluation of a Vascular Coupling Device for End-to-End Anastomosis: A Finite Element Analysis*," Journal of Medical Devices,* Vol. 10, No. 3, pp. 011003(1-7), 2016. DOI*:* 10.1115/1.4031810

46. Nikki Davidoff, David Au, Benjamin Brooks, Bruce K. Gale, Amanda Brooks, "Maximizing Fibroblast Adhesion on Protein-Coated Surfaces Using Microfluidic Cell Printing," *RSC Advances*., Vol. 5, pp.104101 – 104109, 2015.

47. Harikrishnan Jayamohan, York R. Smith, Lauryn C. Hansen, Swomitra K. Mohanty, Bruce K. Gale, Mano Misra, "Anodized titania nanotube array microfluidic device for photocatalytic application: Experiment and simulation," *Applied Catalysis B: Environmental,* Vol. 174–175, pp. 167–175, 2015.

48. T. Onur Tasci, William P. Johnson, Diego P Fernandez, Eliana Manangon , Bruce K. Gale, "Particle based Modeling Of Electrical Field Flow Fractionation Systems," *Chromatography*, Vol. 2, pp. 594-610, 2015, doi:10.3390/chromatography2040594.

49. Jiyoung Son, Kristin Murphy, Raheel Samuel, Bruce K Gale, Douglas Carrell, Jim Hotaling, "Non-Motile Sperm Cell Separation Using A Spiral Channel, *Anal. Meth.*, Vol. 7, pp. 8041 - 8047, 2015. DOI: 10.1039/C5AY02205C.

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Editorials

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Book Chapters

1. Harikrishnan Jayamohan, Valentin Romanov, Huizhong Li, Jiyoung Son, Raheel Samuel, John Nelson, and Bruce K. Gale, "Advances in Microfluidics and Lab-on-a-Chip Technologies" in Molecular Diagnostics, 3rd Edition.George P. Patrinos, Philip B. Danielson and Wilhelm J. Ansorge, Eds. Academic Press: New York, 2016

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Invited Conference Papers/Presentations

1. Bruce Gale, "Taking Microfluidics From Research Ideas to a Real Product," in *Proc. ASME 2019 International Mechanical Engineering Congress and Exposition (IMECE), November 10–14, 2019, Salt Lake City, Utah, USA*, IMECE2019-14008, 2019.
2. Bruce K. Gale, "The History and Applications of Electrical Field Flow Fractionation," in *Proc. Of 18th International Symposium on Field-and Flow-based Separations*, Columbia, SC, USA, , May 14-17, 2018.
3. Bruce K. Gale, "The Future Of Diagnostic Labs: Lab-On-A-Chip," 2018 Spring Seminar of the Utah Chapter of the American Society for Clinical Laboratory Science, Salt Lake City, UT, May 4, 2018.
4. Bruce K. Gale and Kevin E. Petersen, "Exosome separation using electrical field flow fractionation and a new continuous SPLITT/FFF approach, in *Proc. Of ACS 2016 Spring Meeting*, March, 13, 2016, San Diego, CA, Paper ANYL 12, 2016.
5. Matt Hockin, Himanshu Jayant Sant, Mario Capecchi, Bruce K. Gale, "Dean flow fractionation of chromosomes," in *Proc. Of SPIE 9705 (Biomedical Optics),* Microfluidics, BioMEMS, and Medical Microsystems XIV San Francisco, CA, February 13, 2016, paper 970502-1, 2016. doi:10.1117/12.2219842
6. Matt Hockin, Himanshu Jayant Sant, Mario Capecchi, Bruce K. Gale, "An Inertial Microfluidic Device for Rapid Purification of Chromosomes," in *Proc. Of RGJ 2015*, S2-L3, Pattaya, Thailand, June 5, 2015.
7. Bruce K. Gale, Raheel Samuel, Harikrishnan Jayamohan, and Himanshu Sant, "Microfluidic Devices for Rapid and Sensitive Identification of Organisms," in *Proc. EMBS 2014,* Chicago, IL, August 28-31, 2014.
8. Bruce K. Gale, "Spinning Disk Platform for Digital PCR," at Molecular Med Tri-con 2013, February 11, 2013, San Francisco, CA.
9. Bruce K. Gale, Microfluidic Tools for PCR and Digital PCR , at *Digital PCR - Applications and Advances*, October 15-16, 2012, San Diego, CA.
10. Bruce K. Gale, "A Microfluidic Toolbox for Biomedical Applications," in *Proc. of Royal Golden Jubilee-Ph.D. Congress XIII*, Pattaya, Chonburi, Thailand, April 6 – 8, 2012, pg. 82.
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12. Bruce K. Gale, "A Microfluidic Toolbox for Biomedical Applications," at the *54th International Conference on Electron, Ion, and Photon Beam Technology and Nanofabrication (EIPBN 2010)*, Anchorage, AK, June 4, 2010.
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105. D. A Chang-Yen, D. Myszka and B. K. Gale, "A PDMS Microfluidic Spotter for Fabrication of Protein Chips and Microarrays," in *Proc. Of LabAutomation 2005, San Jose, CA* January 30 - February 3, 2005

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108. Himanshu Sant and Bruce K. Gale, "Optical Detectors for Miniaturized FFF Systems," in *Proc. Of the 11th International Symposium on Field Flow Fractionation*, Cleveland, OH, October 7-10, 2003.

109. Srinivas Merugu, Nithin Narayanan, and Bruce K. Gale, "Microscale Serial SPLITT Systems," in *Proc. Of the 11th International Symposium on Field Flow Fractionation*, Cleveland, OH, October 7-10, 2003.

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111. Meregu Srinivas and Bruce K. Gale, "Cyclical Electrical Field Flow Fractionation," in *Proc. Of the 10th International Symposium on Field Flow Fractionation*, Amsterdam, Netherlands, July 2-5, 2002.

112. Himanshu J. Sant and Bruce K. Gale, "A Microfabricated Thermal Electric Field Flow Fractionation System," in *Proc. Of the 10th International Symposium on Field Flow Fractionation*, Amsterdam, Netherlands, July 2-5, 2002.

113. Avinash Saldanha and Bruce K. Gale, "Microfabricated Electrical SPLITT System," in *Proc. of the 10th International Symposium on Field Flow Fractionation*, Amsterdam, Netherlands, July 2-5, 2002.

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115. Charles J Robinson, K Briski, B Choi, PD Coppola, T-H Cui, A Dunn, T Ehsan, Bruce K Gale, W Green, AM Hollister, A Jawahar, HF Ji, S Jones, Y Lvov, M McShane, D Mills, J Patterson, S Patton, H Price, S Roerig, M Sahin, R Schubert, W Simms, K Varahramyan, "The Newlane Consortium (Neural Engineering With Louisiana North Excellence) Building Newlanes To Record And Restore Neural Function," in *Proc. of Third Rehabilitation Research and Development Conference: Rehabilitation Research for the Twenty-First Century: The New Challenges*, Arlington, VA, February 10-12, 2002.

116. Mengyan Li, Hua Ai, David K. Mills, Yuri M. Lvov, Bruce K. Gale, "Increasing the Alignment of Smooth Muscle Cells by 100 mm Channels with Micro- and Nano- Technology," in *Proc. of IBE 2002 International Meeting: Interfacing Biology and Engineering*, Baton Rouge, LA, January 18-20, 2002

117. John Glawe, David Mills, and Bruce K. Gale, "Analysis of Cell Organization in a Smooth Muscle Culture Grown On High Aspect Ratio Microstructures," in *Proc. of IUVSTA 15th International Vacuum Congress (IVC-15), AVS 48th International Symposium (AVS-48), 11th International Conference on Solid Surfaces (ICSS-11)*, San Francisco, CA, October 28 - November 2, 2001.

118. Ameya Kantak, Himanshu Sant, Bruce K. Gale, David K. Mills, Yuri Lvov, and Steve Jones, "A Microfabricated Platelet Analyzer," in *Proc. Smalltalk 2001*, San Diego, CA, August 27-31, 2001.

119. Himanshu J. Sant and Bruce K. Gale, “Improved Scaling Models for Electrical and General Field Flow Fractionation Systems,” in *Proc. 9th International Symposium on Field- Flow Fractionation*, Boulder, CO, June 26-29, 2001.

120. Avinash Saldanha and Bruce K. Gale, “A Microfabricated Electrical SPLITT System,” in *Proc. 9th International Symposium on Field- Flow Fractionation*, Boulder, CO, June 26-29, 2001.

121. Bruce K. Gale and Mahesh Thoppil, “A Microfabricated Cyclical Electrical Field Flow Fractionation System,” in *Proc. 9th International Symposium on Field- Flow Fractionation*, Boulder, CO, June 26-29, 2001.

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123. Himanshu J. Sant and Bruce K. Gale, "Improved Models for Geometric Scaling in Field- Flow Fractionation," in *Proc. of the Nineteenth Annual Houston Conference on Biomedical Engineering Research*, Houston, TX, February 8-9, 2001.

124. Bruce K. Gale, Karin D. Caldwell, and A. Bruno Frazier, "Blood and Protein Separations Using a Micromachined Electrical Field- Flow Fractionation System," in *Proc. of the Eighteenth Annual Houston Conference on Biomedical Engineering Research,* Houston, TX, Feb 10-11, 2000.

125. Bruce K. Gale, Karin D. Caldwell, and A. Bruno Frazier, "Scaling Effects in a Micromachined Electrical Field Flow Fractionation System," in *Proc. 8th International Symposium on Field- Flow Fractionation*, Paris, France, Sep. 6-8, 1999.

126. Bruce K. Gale, Karin D. Caldwell, and A. Bruno Frazier, "Characterization of a Micromachined Electrical Field- Flow Fractionation System," in *Proc. 7th International Symposium on Field-flow Fractionation*, Salt Lake City, UT, Feb. 8-11, 1998.

127. Bruno Frazier, Karin Caldwell, Tim Ameel, Bruce K. Gale, and Ian Papautsky, "Micro scale fluid analysis systems: applications and engineering issues," in *Proc. 7th International Symposium on Field-flow Fractionation*, Salt Lake City, UT, Feb. 8-11, 1998.

Invited Workshop Presentations

1. Bruce K. Gale, “Rapid and Inexpensive Microfluidics-Based Tools for Clinical and Environmental Applications,” at the Digital PCR Shortcourse, Molecular Medicine Tri-Con 2013, San Francisco, CA, February 12, 2013.
2. Bruce K. Gale, "Active Components for Microfluidic Manipulation," CAMD / CBM2 2005 Summer Workshop, Baton Rouge, Louisiana, July 25-29, 2005.
3. Bruce K. Gale, Ian Harvey, and Tim Ameel, “MEMS Workshop” sponsored by Korean Government, January 12-16, 2004. Full week course involving lectures and labs for 8 Professors from Korea on MEMS and MEMS education.
4. Bruce K. Gale and Michael J. McShane, “BioMEMS and Biomedical Optics,” Shortcourse Sponsored by Government of Taiwan (ROC), March 6-8, 2001 (Full three days of presentations: Over 100 paid attendees).
5. Bruce K. Gale, “Advanced Bio-MEMS Techniques and Research Applications” BioMEMS workshop at Chicago 2000, the World Congress on Medical Physics and Biomedical Engineering, Chicago, IL, July 22, 2000.
6. Bruce K. Gale, “Introduction to BioMEMS,” Microfabrication Short Course held with the First Annual Louisiana Microsystems Conference, Ruston, LA, April 4, 2000.
7. Bruce K. Gale, Laboratory Instruction in Microfabrication, MEMS Bootcamp, University of Utah, May 1999.

Patents

1. Patent No. 6,136,171, Micromachined Electrical Field- Flow Fractionation System; Bruce K. Gale, A. Bruno Frazier, and Karin D. Caldwell
2. *Patent No. 8,210,119, Spotting device and method for high concentration spot deposition on microarrays and other microscale devices; Bruce Gale, David Chang-Yen, and David Myszka.
3. *Patent No. 8,211,382, Microassay with internal referencing; David Myszka, Bruce Kent Gale, Joshua Wayne Eckman, and Sriram Natarajan.
4. Patent No. 8,263,392, Methods and compositions related to continuous flow thermal gradient PCR; Bruce Kent Gale, Niel Davenport Crews, Carl Thomas Wittwer.
5. Patent No. 8,269,497, Enhanced fill-factor NMR coils and associated methods; James C. Stephenson, Bruce K. Gale, and Cynthia Furse.
6. Patent No. 8,277,759, Microfluidic Flow Cell, Scott O. Sundberg, Carl T. Wittwer, Bruce K. Gale.
7. Patent No. 8,383,059, Microfluidic interface for highly parallel addressing of sensing arrays, David A. Chang-Yen, Sriram Natarajan, Josh Eckman, Bruce K. Gale, David Myszka.

8. Patent No. 8,395,468, High Field Strength Magnetic Field Generation System and Associated Methods, James C. Stephenson, Bruce K. Gale, and Cynthia Furse.
9. Patent No. 8,535,536 Cross-flow split-thin-flow cell, Bruce K. Gale, Himanshu Sant, Venu Madhav, Srinivas Merugu.
10. Patent No. 8,663,194, Intraocular Drug Delivery Device and Associated Methods, Balamurali K. Ambati, Bruce K. Gale and Srinivas Rao Chennamaneni.
11. Patent No. 8,975,027 Methods and compositions related to continuous flow thermal gradient PCR; Bruce Kent Gale, Niel Davenport Crews, Carl Thomas Wittwer.
12. Patent No. 8,999,726 B2, Microfluidic interface for highly parallel addressing of sensing arrays, David A. Chang-Yen, Sriram Natarajan, Josh Eckman, Bruce K. Gale, David Myszka.
13. Patent No. 9,095,404, Intraocular Drug Delivery Device and Associated Methods, Balamurali K. Ambati, Bruce K. Gale and Srinivas Rao Chennamaneni.
14. Patent No. 9,682,372, Tip overlay for continuous flow spotting apparatus, Bruce K. Gale, Adam Miles, Joshua Wayne Eckman, Sriram Natarajan, Jim Smith Mark Eddings
15. Patent No. 9,682,396, Dual flow cell fluid delivery systems, Joshua W. Eckman, Adam Miles, James Smith, Christopher Morrow, Bruce K. Gale
16. Patent No. 9,877,973, Intraocular Drug Delivery Device and Associated Methods, Balamurali K. Ambati, Bruce K. Gale and Srinivas Rao Chennamaneni.
17. Patent No. 9,931,121B2, Methods and devices for connecting nerves, Jayant P. Agarwal, Bruce Kent Gale, Himanshu Jayant Sant, Keng-Min Lin
18. Patent 10,300,450 Method and device for depositing a substance on a submerged surface, Bruce K. Gale, Joshua W. Eckman, Adam Miles, Christopher Morrow, James Smith, Sriram Natarajan, Mark Eddings.
19. Patent 10,667,816 Vascular Coupling Device, Jay Agarwal, Bruce K. Gale, Huizhong Li, Himanshu Sant.

Pending Patent Applications

1. Appl. No. 20070059156, Rotary centrifugal and viscous pumps: Danny Blanchard, Phil Ligrani, Bruce Gale
2. Xurography: Rapid Prototyping Of Micro-Structures Using A Cutting Plotter: Dan Bartholomeusz, Sung Lee, Ameya Kantak, Merugu Srinivas, Himanshu Sant, Ronald Boutte, Bruce K. Gale, Charles Thomas
3. Diffusion Membrane Micropump, Mark Eddings and Bruce Gale
4. Ultra-Fast PCR Microchip with Real Time Melting Analysis, Niel Crews, Bruce Gale, Carl Wittwer
5. *Automated Arterial Anastomotic Device (multiple applications for different designs), Jay Agarwal, Bruce Gale, Himanshu Sant, Huizhong Li, Cody Gehrke, et. al.
6. Biodegradable Drug-Delivering Nerve Conduit, Jay Agarwal, Bruce Gale, Himanshu Sant, Keng Min Lin
7. *Endo-Contact Lens to Protect the Cornea During Cataract Surgery, Bala Ambati, Bruce Gale, Nathan Gooch
8. Circuit Modification of Electrical Field Flow Fractionation Systems for High Resolution Separations of Sub 100nm Nanoparticles and Macromolecules, Bruce Gale, Onur Tasci, William Johnson
9. *Multiplexed Cell/Tissue Response Assays-Integrated Microfluidic Spotting and Imaging Technology, Bruce Gale, Josh Eckman, Jim Smith
10. Sperm Separation Device, Bruce Gale, Jim Hotaling, Douglas Carrell, Kristin Murphy, Jiyoung Son
11. U.S. Provisional Application No. 62/528,339, filed July 3, 2017, entitled “Rapid Non-Destructive Genetic Material Collection
12. Methods and devices for connecting nerves, US 2019 / 0038290 A1, Jayant P. Agarwal, Bruce Kent Gale, Himanshu Jayant Sant, Pratima Labroo, Jill Shea.
13. Thermal gradient plug flow microfluidic devices for extreme PCR, US20180093273A1, Raheel Samuel, Bruce Gale, Alex Jafek, James Trauba, Kenneth Aston

Other Invention Disclosures

U-3430	Parallel and Serial SPLITT Systems (or combinations)
U-3431	FFF Channel Design to Reduce end Effects
U-3432	Design for SPLITT System with no Splitter (Or Some Version of a Microfabricated Electrical SPLITT System)
U-3433	Cyclical Thermal FFF

U-3434	Design of Thermal FFF
U-3435	Design of Thermal Electrical FFF
U-3550	Single and Double Disk Viscous Micro-Pump
U-3684	A Method for Creating Monolithic PDMS Waveguides Structures Within a PDMS Microfluidic System
U-3685	A Thermally-defined Monolithic Polydimethylsiloxane Waveguide Fabricated on a Polydimethylsiloxane Substrate
U-3686	Integrated Optical Waveguide Chemical and Particle Detection Method Relying on Evanescent Interactions
U-3708	Polydimethylsiloxane (PDMS) Fluidic Packaging with a Reusable Syringe Needle Compression Fitting
U-3744	Process/Technique for Fabricating a Microneedle Array
U-3810	Osmotically-Driven Dispense Pump for Use in High Pressure and High Temperature Applications
U-3862	Method of Patterning Aluminum Oxide Membranes
U-3863	Multi-DNA Extraction Chip Based on an Aluminum Oxide Membrane
U-3893	Novel Manufacturing of Microdispenser or Microneedles: Materials and Methods
U-3894	Diffusion Membrane Micropump
U-3896	Sample Collection and Spot Cleaning Technique Using a Continuous-Flow PDMS Microfluidic System
U-3963	Use of Permanent Magnets and Flux Concentrators/Shunts to Utilize NMR for In-Ground Measurements
U-4140	Integrated Pneumatics and Electronics Card
U-4154	In-situ Heating and Actuation Mechanism Using Conductive Waxes (or Similar Materials), Methods and Applications Thereof
U-4234	CFM Flow Cell with Switching of Solutions
U-4281	DNA Quantification Method with Nanoporous Aluminum Oxide Membrane
U-4282	High Diodicity Microvalve
U-4283	Shuttle Gradient Multiplex MicroPCR Chip
U-4460	Continuous Protein Separations Using SPLITT System
U-4464	Surface Modified Nanoporous Substrate for High Sensitivity and High Density Microspot
U-4499	Continuous Protein Separations Using SPLITT System
U-4689	Nanoscale Electrochemical Biosensor
U-4944	Refilling Mechanism to Stabilize a Free-Floating Intraocular Capsule Drug Ring (CDR)
U-4945	Refilling Mechanism to Stabilize a Free-Floating Intraocular Capsule Drug Ring (DCR)
U-4956	Electrostatically Actuated High Density Pneumatic Microvalve Array
U-4959	An Intraocular Capsular Drug Ring With Biosensing Capabilities
U-5143	Shorts/Pants with Integrated Pressure Alleviating Bladders
U-5144	Annular Device for Intramedullary Infusion and Aspiration
U-5532	A Novel Ferrofluidic Magnetic Micromixer
U-4638	Assays for Anti-drug Antibodies Using Label-free Detection and Continuous Flow Microfluidics
U-4715	Multichamber Disposable Microfludics Device
U-5035	Subconjunctival Drug Delivery Device for Long-Term Glaucoma Therapy
U-5027	High Throughput Intestinal Permeability Assay
U-4959	An Intraocular Capsular Drug Ring With Biosensing Capabilities
U-5534	Cyclical Electrical SPLITT Systems for High Resolution Continuous Separations of Sub 100nm Nanoparticles and Macromolecules

U-5531	Utilization of Microfluidics Technology for Extraction of Chorionic Fluid of Zebrafish Embryos for Genotyping Zebrafish
U-5616	Complete blood count device
U-5631	Schlemm's Stent-Sieve
U-5653	Automated Pathogen Detection System
U-5082	Endo-Contact Lens to Protect the Cornea During Cataract Surgery
U-5720	Interstitial Fluid Extraction Device
U-5742	Microfluidics-based human sperm cell separation, sorting, and cryopreservation device
U-5889	Wearable device for pressure ulcer prevention
U-6163	Thermal Gradient Plug Flow Microfluidic Chip for Extreme PCR
U-6183	Bioresorbable Drug Delivery Peripheral Nerve Wrap
U-6221	Self contained bioreactor for repair of segmental bone defects
U-6337	Bioresorbable Drug Loaded Peripheral Nerve Wrap Capable of Extended Localized Delivery of FK506
U-6361	Microfluidic system for sperm separation and enrichment from various types of sperm samples
U-6389	Rapid non-destructive genetic material collection for genotyping of zebrafish
U-6470	Injectable Hyaluronic Acid Hydrogel Drug Delivery System for Extended Release of a Local Anesthetic to Treat Post-Operative Pain

Service to the Department and University

January 2019 – present	Advisor, University of Utah National Society of Black Engineers Chapter
August 2013 – June 2018	Executive Director, University of Utah Nanofabrication Lab
October 2016 – May 2017	Member, ME Dept Design Search Committee (hired Yong-lin Kong)
August 2016- July 2018	Member of College of Engineering RPT Committee
June 2015 – March 2018	Member, Senate Advisory Committee of Review of Administration
August 2014- August 2017	Member of ME Research Committee
August 2013 – May 2014	Chair, ME Dept Design Faculty Search Committee, (hired Jiyoung Chang and Roseanne Warren)
May 2012 – August 2013	Associate Director, University of Utah Nanofabrication Lab
October 2010 – May 2011	Member, ME Dept Design Search Committee (hired Shad Roundy)
August 2010 – July 2013	Senator, Faculty Senate
June 2010 – July 2016	Member, Innovation Scholars Academic Steering Committee
October 2009 – May 2010	Member, ME Dept Manufacturing Search Committee (hired Bart Raeymakers)
August 2009 – June 2018	Chair, University Conflict of Interest Committee
August 2006 – June 2018	Member, University Conflict of Interest Committee
November 2005 – present	University of Utah Technology Review Board
September 2005 – July 2008	University International Requirement Committee
August 2004 – May 2005	ME Seminar Coordinator
January 2004 – May 2004	URT Selection Committee
August 2003- August 2004	Member of ME External Relations Committee
August 2003- May 2004	Member of Design Faculty Search Committee (hired Will Provancher)
August 2003 – May 2004	IGERT Seminar Coordinator
August 2002- July 2015	Member of ME Curriculum Committee
February 2002- present	Member of College of Engineering Nanofabrication Lab Executive Committee
January 2002- August 2003	Member of ME Public Relations Committee
1999- 2001	Internal advisory committee for the Institute for Micromanufacturing (La Tech)
1999- 2001	Biomedical Engineering program Webmaster (La Tech)

Service to the Academic Community

April 2019 – Nov 2019	Member of Organizing Committee IMECE 2019, Salt Lake City, Utah.
June 2017 – May 2018	Member of Organizing Committee for18th International FFF Symposium

Dec 2016 - October 2017	Member of Organizing Committee (Sponsorship Committee) for MicroTAS 2017 in Savannah, GA. Served as Session Chair.
February 2017	Alternate Separations Workshop (AltSep) on Electrical Separations
June 2015 – May 2016	Member of Organizing Committee for17th International FFF Symposium
June 2013 – present	Tenure and promotion external reviews (10 completed)
January 2013 – present	Associate Editor, *Journal of Micromechanics and Microengineering*
June, 2013 – October 2014	Chair, FFF 2014 Organizing Committee
January 2012 – present	Permanent Member of the Scientific Committee for FFF (sponsor organization of international field flow fractionation symposia)
June 2010 – May 2011	Member of Organizing Committee for15th International FFF Symposium
Nov 2010 – Oct 2011	Member of the NanoUtah 2011 Organizing Committee
Feb 2010 – present	Organizer of science fairs and judge at Viewmont Elementary and Riverview Jr High
Feb 2010 – Nov 2011	Session Organizer, AICHE Annual Meeting 2010 in Salt Lake City, November 2010
October 2009 – Oct 2010	Chair of the NanoUtah 2010 Organizing Committee
January – October 2009	Member of the NanoUtah 2009 Organizing Committee
November 2007	Member of the Program Committee - Invited Speakers for American Physical Society – Division of Fluid Dynamics Annual Meeting, 2007
June 2007	Chair of Organizing Committee for13th International FFF Symposium
November 2006	Session co-chair BioMEMS and Microfluidics: Biomedical Diagnostics, AICHE 2006
September 2006	Proposal Reviewer for Canadian Foundation for Innovation
June 2006 to present	Proposal Reviewer for NIH (16 panels and site visits)
January 2005 to present	Program committee for Microfluidics, BioMEMS, and Medical Microsystems III - XII
March 2004	Organizer of Nanoscale Separations Track at ACS National Meeting
April 2003 to present	NSF Panel Reviewer (20 separate panels, over 200 proposals reviewed)
January 2003	Chair of BioMEMS and Nanofabrication Session at SPIE 2003
May 2001	Reviewer of research proposals for DOE
February 2001	Chair of BioMEMS session at HSEMB Conference
November 2000	Chair at two sessions of Advanced Technology Workshop on MEMS Packaging
October 1999	Chair at several sessions of Joint BMES/EMBS Conference
1997-1999	Co-President, IEEE Engineering in Medicine and Biology Chapter, Univ. of Utah
October 2002-present	Reviewer for *Journal of Nanoscience and Nanotechnology, Journal of Microelectromechanical Systems*, *Clinical Chemistry*, *Journal of Micromechanics and Microengineering*, *Journal of Measurement Science and Technology*, *Electrophoresis*, *Analytical Chemistry*, *IEEE- Transactions on Biomedical Engineering, Journal of Microfluidics and Nanofluidics, Sensors and Actuators A: Physical, Sensors and Actuators B: Chemical, Lab on a Chip, Applied Physics A, IEEE Sensors, Physics of Fluids*, *Journal of Fluids Engineering*, *Integrative Biology, Pharmacogenomics, Langmuir, Journal of Materials Engineering and Performance, Nanomedicine & Nanobiotechnology, Chromatography, Analytical Methods*

Professional Affiliations

2018-present	Member, American Society of Mechanical Engineers (ASME)
2001-2003	Member American Society for Engineering Education (ASEE)
2001-2003	Member, American Chemical Society (ACS)
2000-2002	Member, Institute for Microelectronics and Packaging Systems (IMAPS)
1997-present	Member, Institute for Electrical and Electronics Engineers (IEEE)
1997-present	Member, IEEE Engineering in Medicine and Biology Society (EMBS)

EXHIBIT N

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CYTIVA SWEDEN AB, and GLOBAL LIFE SCIENCES SOLUTIONS USA LLC, Plaintiffs v. BIO-RAD LABORATORIES, INC., Defendant.	C.A. No. 18-1899-CFC Consolidated **DEMAND FOR JURY TRIAL** **HIGHLY CONFIDENTIAL (TECHNICAL) – ATTORNEYS' EYES ONLY**

REPLY EXPERT REPORT OF DR. BRUCE GALE

controlled fluid flow to a column, that separates components in a liquid, as I showed in my experiments.

35. Next, Dr. Wereley claims the court rejected the definition of a liquid chromatography system that I have been using. He provides no citation for that claim. I can address it if he does.

36. In any event, as I described in the prior paragraphs and in my opening report, the 2040 System does have detectors of the same type as mentioned in the asserted patents. Nor is it of any moment that some of the detectors in the 2040 System require calibration as Dr. Wereley claims is a basis for distinguishing the 2040 System. Wereley ¶ 325. There is no description in the asserted patents for how the detectors must function and certainly nothing that excludes something from being a detector simply because it must be calibrated. I understand that it is improper to read limitations into the claims from the specification and that it is even more improper to create limitations that are not even mentioned in the specification and import those into the claims. Thus, the need to calibrate a sensor does not disqualify it from being a detector under the asserted patents. If it does, detectors in the Bio-Rad accused systems would have to be disqualified. I confirmed with Ms. Schaefer, one of the Bio-Rad specialists in the NGC, that [redacted]. The same is true of the AKTA systems. *See e.g.*, GEHCDEL123052 at GEHCDEL123222 ("If pH will be measured during the chromatographic run, the pH monitor should be calibrated before the run is started.").

37. Next, Dr. Wereley claims that the 2040 System is not an automated liquid chromatography system because before running chromatography on the instrument, a significant amount of advanced planning went into the run like calculating salt and buffer concentrations, identifying a starch that would absorb the dyes and determining the concentration of methanol.

Wereley at ¶¶ 333, 339. It is difficult to understand Dr. Wereley's argument. The fact that calculations had to be done before performing the chromatography to determine what buffers to use, what kind of column to use and what liquid constituents to use to illustrate the separation that the 2040 System liquid chromatography system would perform does not mean it is not a liquid chromatography system. It simply means that the parameters of that particular separation had to be determined. I do not consider the time spent on the calculations to be anything out of the ordinary. In fact, the system was able to perform liquid chromatography quite easily. Dr. Wereley fails to consider that when workers buy machines now, they usually have field service representatives who have used the particular machines hundreds if not thousands of times come on site to teach the user how to use the machine. That did not happen here. Rather, we were able to figure out how to use the machine relatively easily simply from reading the manual. Moreover, many if not all of the same type of calculations would have to be performed even if using the Bio-Rad or Cytiva machines. I confirmed this with one of Bio-Rad's field specialists, Katie Schaefer. Ms. Schaefer told me that she had experience as a graduate student using the Akta machines as well as extensive experience using the NGC. Mr. Schaefer confirmed what I understood, and what is known by anyone of ordinary skill who actually performs chromatography on an instrument, that the first time you run a particular LC separation experiment, you will have to do the types of calculations we did to determine buffers, concentrations flow rates, column material etc. That is as true for the Plaintiffs' Atka machines and, Bio-Rad's accused machines as it is for the 2040 System prior art system.

38. If Dr. Wereley actually believes that one could approach a Plaintiff or accused machine the first time running an experiment and somehow type in what you wanted to do and then hit a button and have the machine run, he is clearly mistaken. On the Bio-Rad machine, for

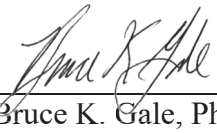
example, the only information that is calculated on its own relates to the columns. If you identify a column for use which happens to have been preloaded on the instrument, it will recognize the volume and the maximum pressure. It can then insure that instrument is not set for example to exceed the maximum pressure. But that is a far cry from what Dr. Wereley seems to be saying.

39. Additionally, I asked Ms. Schaefer about the amount of training that a Bio-Rad customer typically receives upon purchasing a machine. In addition to the fact that she said [redacted]

40. Given those metrics, I believe we spent much less time getting the 2040 System machine to perform chromatography. We had no one come in to help us learn how the system operated. All we had was the user manual. Moreover, as I said, the user interface on the 2040 System was not as easy to use as more modern interfaces. That slowed us down a little as well. Nonetheless, we were able to get the 2040 System to perform a chromatography experiment in an amount of time and with an amount of work that was less than or at least in the same range as a user who purchases an accused Bio-Rad device

41. Moreover, to the extent that Dr. Wereley is claiming that some never used before programming had to be done to modify the 2040 System machine to perform chromatography, that is not the case and it is a distortion of the process. The "programming" that Dr. Wereley refers to in paragraphs 340-349 of his rebuttal report is merely selecting from the menu driving system how long and in what order certain components of the system would operate. Those are

DATED: November 11, 2020



Bruce K. Gale, Ph.D.

EXHIBIT O

THIS EXHIBIT HAS BEEN REDACTED IN ITS ENTIRETY

EXHIBIT P

THIS EXHIBIT HAS BEEN REDACTED IN ITS ENTIRETY

EXHIBIT Q

THIS EXHIBIT HAS BEEN REDACTED IN ITS ENTIRETY

EXHIBIT R

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

- - -

GE HEALTHCARE BIO-SCIENCES AB, GE HEALTHCARE BIO-SCIENCES CORPORATION, and GENERAL ELECTRIC COMPANY,	:	CIVIL ACTION
Plaintiffs,	:	
vs.	:	
BIO-RAD LABORATORIES, INC.,	:	
Defendant.	:	NO. 18-1899-CFC

- - -

Wilmington, Delaware
Thursday, May 14, 2020
10:30 o'clock, a.m.
***Telephone conference

- - -

BEFORE: HONORABLE COLM F. CONNOLLY, U.S.D.C.J.

- - -

APPEARANCES:

SHAW KELLER LLP
BY: JOHN W. SHAW, ESQ.

-and-

Valerie J. Gunning
Official Court Reporter

if you look at the same portion of the patent, there's a UV monitor. Obviously, that's going to be electronic.

THE COURT: All right. So let's talk about the prosecution history then. I mean --

MR. MILLER: Okay.

THE COURT: -- I think Mr. Bilsker makes a compelling argument that looks pretty clearly and unequivocally, your client, or the applicant for the patent I should say made clear, clearly and unequivocally, as far as I'm concerned, that there are two sections, and that's what differentiates this patent from Bergstrom and Hess. So why don't you walk me through your response to that.

MR. MILLER: Okay. So, first of all, I think it's important to note that we don't disagree that there's going to be a separation from the fluidics section and non-fluidics section, but, first of all, there can be other sections.

As you pointed out, the claim language talks about a fluidics section and a non-fluidics section, and all the claims use the transitional phrase comprising, which means there can be other sections.

So even if you draw the circle --

THE COURT: That wasn't how you distinguished Bergstrom and Hess. I mean, you pretty explicitly said to the Examiner, hey, what makes this different is we've got

complete separation of the fluidic and the non-fluidic section. And, incidentally, I think that's consistent with, you know, your slide, which says, hey, the phrase itself tells you, there's no fluidic component in the non-fluidic section.

MR. MILLER: Well, our argument on non-fluidics in the fluidics section, that's what I called the non-fluidics section.

THE COURT: As opposed to the fluidics section. I mean, it's a referential definition. Right? It says, this is a non-fluidics section as opposed to the fluidics section.

MR. MILLER: Well, yes, but where is the negative language that says that there can't be? I would submit, Your Honor, that when it says fluidics, that just means there can be fluidics components. It doesn't say that there can't be anything else. There's going to be other things. There's going to be the pressure sensors, there's going to be the UV monitors. There's going to be all kinds of other things, and the patent explicitly teaches that.

So why don't you turn to the prosecution history.

So, first, let's talk about Bergstrom. We addressed Bergstrom in our brief, by the way. I'm not sure where they are coming from with that.

THE COURT: Where in your brief? Why don't you point to me in your brief where you address it.

MR. MILLER: One second, please. I need to find it. It's on page 867.

THE COURT: Okay. Go ahead.

MR. MILLER: So in Bergstrom, again, I'm looking at their slide 58.

THE COURT: Their slide? Okay.

MR. MILLER: Well, they have the Bergstrom slide here.

THE COURT: Yes.

MR. MILLER: This is distinct in Bergstrom. Again, it says the detector also includes a processing unit. This is actually an important point. Liquid chromatography systems have detectors in them.

As far as I know, every model of a liquid chromatography system has a detector in them and the detector is going to be on the wet side. So our argument is actually consistent with what is being said here because it makes a distinction between a detector and it says it includes a processing unit, which is very likely to be electronic in nature. So in the systems in the patent, there has to be a detector, and it's not going to be inside the box, because that would be a fluidics component.

THE COURT: Right.

MR. MILLER: So in Bergstrom, in that particular piece of prior art, I guess they were all one piece, and so it says that they're going to be -- there's going to be electronic -- it says, liquid and electrical parts sit side by side in the module in the baseplate.

So, again, what they are saying is that, hey, look, there's no non-fluidics section here. They are not saying, and the word all appears nowhere in any of this prosecution --

THE COURT: No, but it's saying liquid and electrical parts sit side by side as opposed to your invention. But your invention -- I mean, if you want to buy -- you know, you are saying that, well, no, we've got a pH electrode that's electric which sits by side with fluidics components. You are saying it's actually attached to a fluidics component.

MR. MILLER: Yes. It's inside of something that's inside of the pH module.

THE COURT: How do you reconcile that with the statement that says, what distinguishes and makes patentable your patent is that, "liquid and electrical parts sit side by side in Bergstrom but they don't in yours"?

MR. MILLER: Because it's saying in the non-fluidics section, there aren't going to be -- in the non-fluidics section, there won't be any electronics. It

So basically, what you are saying makes sense to me, I think. Let's hear from Bio-Rad says.

MR. BILSKER: Absolutely not, Your Honor.

THE COURT: Why not?

MR. BILSKER: Because again, it begs the question. What is a section? They want to say you can have a fluidics section, because if I have -- if I have this fluid line here, I will draw a circle around this fluid line and I'm going to call that a fluidics section, and then if I have more fluidics on the side and they're next to electronic parts, I'm not going to call those part of the fluidics section. Those are a different section. And that is completely inconsistent with the representation that they made about Hess.

And let me just -- the reason I asked whether he was pointing to page 1477 is because 1477 is talking about Mourtada. It's not talking about Bergstrom.

And if we go back to the slides on Hess --

THE COURT: No, no. Don't go there yet. Let's just finish up. You see, look, if you've got --

MR. BILSKER: Again, that's not what they claimed.

THE COURT: Just hold on a second, please. I mean, what I understand the compromise is, essentially, if you agree with Bio-Rad, that if you have a non-fluidics

section, there can't be any fluidics in it, and a fluidics section would mean there's no non-fluidics in it.

But could there be, in addition to those two sections, a third section, and you could have a mix. And as I look at claim 1, for instance, of the '591 patent, it has an external fluidics section. It has to have one. It has to have an internal non-fluidics section. So both of those sections would have to exist and would have to have in one case, the fluidics section, no non-fluidic component. In the second case, the non-fluidic section could not have any fluidic component.

And then it has to have a separate section, which is something distinct and different and is not within those two sections, and Bio-Rad here is saying you can't live with that.

MR. BILSKER: Absolutely not. Again, it begs the question. What is the section at that point? So I have a module and I have an outside part of it and I'm going to split it up into little, little piles, and I'm going to say, hey, I've actually got 45 different sections here on this module, 45 different sections on the outside. You know, I don't -- there's a bunch of electronics, but they're all on the top half. So because they're on the top half, I'm going to call only the bottom half my fluidics section and I'm not going to call the top half my fluidics section, and that's

just not what they said during the prosecution. The section was defined as all parts of that type, and that's again, if we go through slide 58, 59 --

THE COURT: But I guess what I'm getting at it is, I think, GE, would you agree then, would you agree to Bio-Rad's construction?

MS. SKLENAR: No, because our issue with their construction is that it says essentially all electronics for the module, for the entire module have to be in a non-fluidics section. And, again, that would allow --

THE COURT: Fair enough. So what if it just said though, a section -- yes. I mean, you know, here's where I am. I will just tell you right now.

So I'm not able to accept GE's position that on one hand a non-fluidic section can contain fluidics. On the other hand, a fluidics section cannot contain non-fluidics. On the other hand, the patent uses the indefinite article, so it contemplates one or more sections, and the Federal Circuit has said, understandably, that the indefinite article does not mean all.

So that is what I find problematic about Bio-Rad's construction, is they want to say all the fluidic components.

MS. SKLENAR: Yes. I apologize.

THE COURT: That's all right. You know, but GE,

you know, I can't live with the way you want to interpret it.

MS. SKLENAR: Yes. If we can put all of our cards on the table.

THE COURT: Well, that's helpful.

MS. SKLENAR: The reason we're fighting about this is because Bio-Rad wants to argue for noninfringement that they have some electrical components like lights that are in the panel member, so neither of the sections we're talking about, the fluidics or non-fluidics, but are in the panel member.

So, for example, what we see in Figure 4A at 28, they want their construction so they can then turn around and say, we don't infringe because we don't have all of our electrical components in one section. And what we're submitting -- and, again, we are modifying our approach. We are willing to agree that a fluidics section cannot have electronics or electrical components, but what we can't live with is this notion that somehow you could get outside of the scope of this claims by putting little lights in a different section.

THE COURT: But that is not before you. Right? You kind of did an all-or-nothing in your proposal. I mean, it seems to me you could have been more judicious in the proposal and then left this issue for trial and figure it

out.

So why don't we just step back and let's go with, I'm looking at page 94 of your brief where we've got the competing construction proposals for fluid handling section. Right? And you've got a section of the interchangeable fluid handling unit that includes fluidics components.

So why don't you just change that to be consistent with your construction of a non-fluidic section and say that this would be a section of the interchangeable fluid of the interchangeable fluid handling unit that does not include electrical components.

MS. SKLENAR: And we're willing to do that, Your Honor. It's the all issue we can't live with.

THE COURT: Okay. But, you know, then that's fair and I think that's a legitimate complaint. So here's where I am. That's how I'm going to interpret these terms.

I'm going to interpret non-fluidics section to mean, "a section of the interchangeable fluid handling unit that includes electrical components and does not include fluidics components."

I'm going to construe a fluid handling section to mean, "a section of the interchangeable fluid handling unit that includes fluidics components and does not include non-fluidics components." And that seems to me to be the

most reasonable construction. That is consistent with what I think were clear and unequivocal statements to distinguish this patent from Bergstrom and Hess, because the basis of the distinctions to the Patent Examiner were that this patent had two sections that, at least two sections, one is non-fluidic, one is fluidic, that are separated completely and that do not contain components of the other section.

That does not, however, preclude the possibility that there are other sections that are in the invention, and that's important because that is consistent with the use of the indefinite article, which is inconsistent with Bio-Rad's insistence that "all," either fluidic or non-fluidic components, are in the respective handling unit.

So that actually seems to me is the right result in this case and I'm going to construe then these last group of terms in that manner.

All right. Is there anything else for me to construe?

MS. SKLENAR: Nothing from plaintiff, Your Honor.

MR. BILSKER: Mr. Bilsker. None.

THE COURT: Okay. I'm going to ask the plaintiff to submit within a week from today a written order of the claim chart and the basis of my rulings are set forth in today's telephone conference.

I read the briefs carefully. I've articulated the general basis of my rulings. I'm cognizant that there's de novo review in the Federal Circuit, so that really no matter what I say has really no consequence, but I appreciate the briefing and the arguments of the parties today. And if you will just submit that order that is consistent with my rulings today within a week, I will sign it forthwith.

Anything else from the plaintiffs?

MS. SKLENAR: Nothing, Your Honor. Thank you so much for your time.

THE COURT: Anything from the defense?

MR. BILSKER: I was just curious about the transcript, but I guess we can handle it.

THE COURT: What do you mean?

MR. BILSKER: Whether we would get the transcript just to make sure that the order is consistent with the transcript. I was having a little trouble writing as quickly as you were speaking.

THE COURT: Well, let's actually, before we leave, where is there any ambiguity in what I've ruled on in your mind?

MR. BILSKER: I don't think there's ambiguity. I just didn't have the exact words that you said. I didn't get a chance to write them down exactly. Maybe my associate

did. That's all I was saying.

THE COURT: No, that's fair. And, really, I think the big point is, it is kind of the thing that disturbed me from the beginning with the plaintiffs' argument, is on those last two, the fluidics and the non-fluidics, I just interpreted it as far as I'm concerned in a manner that's consistent, and I think that Bio-Rad even agreed insofar as it being consistent. That's the big distinction there.

So, okay. If because of the current situation you need more time to get the order in, to get the transcript ready, that's fine, but at least as of now we'll set it for a week from today, and the obligation will be on plaintiffs to submit the proposed claim construction order. Okay?

Everybody have a great day. Stay safe. Thanks very much. Bye-bye.

(Counsel respond, "Thank you, Your Honor.")

(Telephone conference concluded at 1:12 p.m.)

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EXHIBIT S

HIGHLY CONFIDENTIAL (TECHNICAL) - ATTORNEYS' EYES ONLY

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

CYTIVA SWEDEN AB and GLOBAL LIFE SCIENCES SOLUTIONS USA LLC,	)	
Plaintiffs,	)	C.A. No. 18-1899-CFC Consolidated
v.	)	
BIO-RAD LABORATORIES, INC.,	)	
Defendant.	)	

OPENING EXPERT REPORT OF STEVEN WERELEY, PH.D.

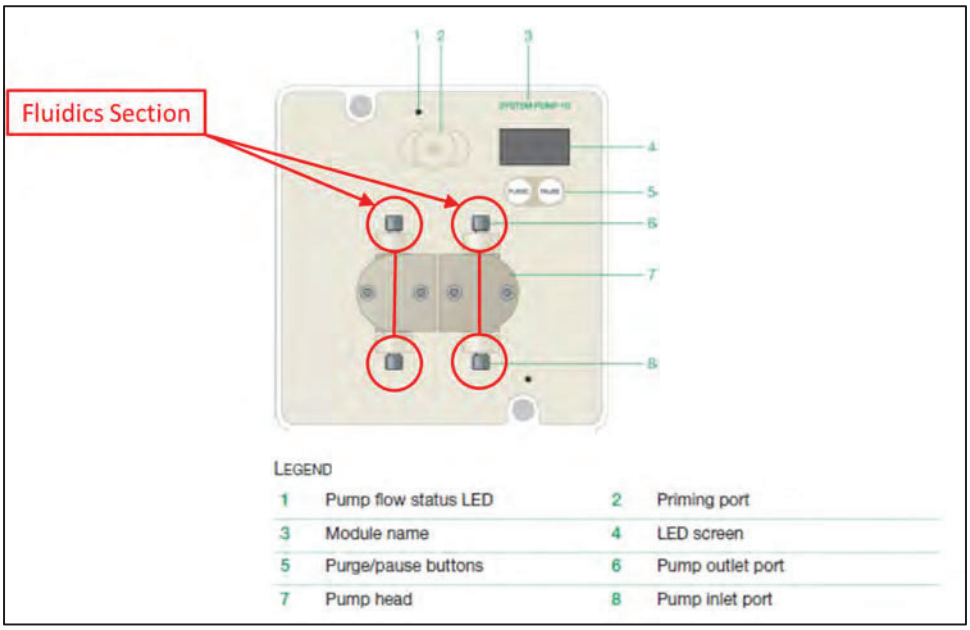
[redacted]

Ex. 56 (BRGEDEL000450753) [redacted]

108. Mr. Chapman testified that these specifications were met for the pump modules (Chapman Tr. 529:12-530:17) and sample inject valve module (Chapman Tr. 528:16-529:10).

109. These documents and Mr. Chapman's testimony demonstrates that the "fluidics section" for each of these modules, *e.g.*, the two system pump modules and the sample inject valve module "*include[] fluidics components*," just as the Court's claim construction requires.

110. The fluidics section for the system pump modules used in the NGC system is as follows:



Ex. 211, pp. 28-29. Note that this figure annotated to show hidden portions of the fluidics section, *i.e.*, a simplified illustration of the flow path within the fluidics section.

111. Note that the NGC Instrument Guide illustrates the F10 pump module, but the F100 pump module is essentially identical for purposes of this infringement analysis, meaning that the structure corresponding to the recited fluidics section is the same.

112. Note also that this portion of the Instrument Guide does not illustrate the priming ports that can be on the system pump modules. These can be seen in the

X. CONCLUSION

705. For the reasons stated above, it is my opinion that Bio-Rad infringes the Asserted Claims. I respectfully reserve the right to supplement, augment, or amend my opinions and/or to supplement my expert report.

Dated: September 11, 2020

Steven Wereley, Ph.D.